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Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries

Botswana

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Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries

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Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries: Botswana

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Foreword

by Roy Widdus, Ph.D.
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The study described in this report is one of a series initiated and designed by the Initiative on Public-Private Partnerships for Health (IPPPH), supported principally by the UK Department for International Development, and undertaken in association with the Institute for Health Sector Development based in London. The series also includes country studies on Uganda (the pilot country studied in 2003), Sri Lanka and Zambia. A 'Synthesis Report' covers conclusions and recommendations across all countries and programmes evaluated.

IPPPH was established in 2000, in part to develop a solid evidence base on public-private 'partnerships' for health so that the benefits of such collaboration for populations afflicted by poverty could be maximized and potential risks ameliorated.

IPPPH identified early in its existence the need for the type of study described in this report in response to a range of questions being raised about 'partnerships' addressing drug access in low and middle-income countries that included donations or discounted pricing from pharmaceutical companies. Funding was provided by the UK Department for International Development (DFID) with supplementary support from the general contributors to IPPPH, namely, the Bill & Melinda Gates Foundation, the Global Forum for Health Research, The Rockefeller Foundation, and the World Bank.

The study design benefited from wide input, including staff of the World Health Organization and the Study Advisory Committee. A team of consultants was selected with assistance from the Institute for Health Sector Development, London, an organization specializing in evaluation of health systems issues in developing countries. Ultimate approval of the study protocol rested necessarily with the IPPPH as the agent responsible to the principal funder, DFID, along with the national government counterpart.

All members of the consultant team are independent of the pharmaceutical industry and IPPPH. None of the national consultants had any direct programmatic or managerial responsibility for any of the programmes examined. However, their knowledge of the national health system and key information sources greatly benefited the study.

The IPPPH Secretariat, along with the Study Advisory Committee, offered suggestions for clarification of the draft text of the report and is pleased to publish the consultant team's final report in its entirety, as a significant contribution to understanding the actual impact at national and field level of these diverse collaborative ventures.

This study can stand alone but is part of an ongoing IPPPH programme of activities related to the overall goal of assessing public-private collaboration to improve access to pharmaceuticals for those affected by diseases associated with poverty. However, as noted above, it is part of a series undertaken to serve this general goal. Readers should consult the 'Synthesis Report'[1] for general conclusions on those issues addressed in this series of studies. This series of studies adds considerably to the evidence base on 'access' public-private partnerships but further issues need to be considered. The Foreward of the Synthesis Report identifies some programmes and issues that this series of studies could not cover.

IPPPH thanks the UK Department for International Development for its financial support, and the excellent consultant team: Nel Druce, Deputy Director, Institute for Health Sector Development, United Kingdom; Joyce Kgatlwane, Essential Drugs Action Programme, Ministry of Health, Botswana; Otsetswe Mosime of Atos KPMG Consulting, Botswana; and Ilavenil Ramiah, Harvard

[1] Impact of Public-Private Partnerships addressing access to pharmaceuticals in selected low and middle-income countries: A synthesis report from studies in Botswana, Sri Lanka, Uganda and Zambia; ISBN 2-940286-21-3

School of Public Health, USA. Nel Druce deserves credit as Team Leader for the study.

Special thanks must go to the many individuals in Botswana who gave generously of their time to the consultant team. We trust the insights of the study will prove useful to them, as well as the broader international community.

Abbreviations

AAI	Accelerating Access Initiative
ACHAP	African Comprehensive HIV/AIDS Partnerships
ACU	AIDS Coordination Unit
AMDS	AIDS Medicines and Diagnostic Supplies
ARIPO	Africa Regional Industrial Property Organization
ARVs	Anti-retroviral drugs
ART	Anti-retroviral therapy
ASU	AIDS/STD Unit
BNDP	Botswana National Drug Policy
CM	Cryptococcal meningitis
CMS	Central Medical Stores
DFID	UK Department for International Development
DMSAC	District Multisectoral AIDS Committees
DPP	Diflucan® Partnership Programme
DRU	Drug Regulatory Unit
FDC	Fixed dose combination
GoB	Government of Botswana
GSK	GlaxoSmithKline
HAART	Highly Active Anti-Retroviral Therapy
IAPAC	International Association of Physicians in AIDS Care
IEC	Information, education and communication
IPPPH	Initiative on Public-Private Partnerships for Health
IPT	Isoniazid Preventive Therapy
KITSO	Knowledge and Training Shall Overcome
MoLG	Ministry of Local Government
MOF	Ministry of Finance
MOH	Ministry of Health
MOU	Memorandum of Understanding
MTP II	The second Medium Term Plan
NAC	National AIDS Council
NACA	National AIDS Coordinating Agency
NASCOD	National Standing Committee On Drugs
NDPs	National Development Plans
NGO	Non-governmental organization
NSF	National Strategic Framework
NVP	Nevirapine
OC	Oesophageal candidiasis
OIs	Opportunistic infections
PEPFAR	US President's Emergency Plan For HIV/AIDS Relief
PMTCT	Prevention of mother-to-child transmission of HIV
PPADB	Public Procurement and Assets Disposal Board
PPP	Public-private partnership
PSC	Parliamentary Select Committee on HIV/AIDS
PSI	Population Services International
R&D	Research and development
SADC	The Southern Africa Development Community
STIs	Sexually transmitted infections
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights
VCT	Voluntary testing and counselling
VDP	Viramune® Donation Programme
WHO	World Health Organization
WTO	World Trade Organization
YOHO	The Youth Health Organisation
ZDV	Zidovudine

Executive summary

This study of public private partnerships (PPPs) in Botswana for improving access to HIV/AIDS related pharmaceuticals is one of a series commissioned in 2003–2004 by the Initiative for Public-Private Partnerships for Health (IPPPH), and funded by the UK Department for International Development (DFID). In addition to Botswana, country studies were carried out in Uganda (2003), Zambia (2004) and Sri Lanka (2004). In Botswana, the study looked at PPPs to improve access to drugs for HIV/AIDS and related conditions, in contrast to the other countries, where PPPs also address tropical diseases not prevalent in Botswana.

The study's remit was to assess the health and health systems impact of the PPPs, looking in particular at issues of ownership, integration, co-ordination, implementation and impact, with a focus on the benefits, challenges, risks and lessons learned in these PPPs, as distinct from other programmes where drugs are competitively procured. The key research question concerns the degree to which the involvement of multinational research and development-based pharmaceutical companies, as partners in supplying free or discounted drugs, facilitates drug availability and access by the poor.

Given its time and resource limitations, this was a rapid and largely qualitative study making extensive use of semi-structured interviews with key informants at national and district levels. Following Ministry of Health approval for the study through the Health Research Development Committee, a range of government and other stakeholders took part in over 50 interviews carried out in May 2004. The study included visits to eight district level public health facilities providing HIV/AIDS related services, including government supported hospitals managed by the corporate mining sector and a faith (mission) based organization.

HIV/AIDS is having a major impact on health, poverty reduction and development objectives across sub-Saharan Africa, and particularly in Botswana. As consensus developed on the severity of the epidemic in the late 1990s, great efforts are now focusing on the technical and financial challenges of providing HIV treatment, based on antiretroviral therapy, as part of the comprehensive response to HIV/AIDS in developing countries. President Mogae announced his intention to develop the national ARV programme in March 2001. In January 2002, Botswana was the first African country to launch a national, public sector ARV programme, and has the greatest number of public sector patients benefiting from free treatment.

Several of the major research-based pharmaceutical companies initiated donation and discounted drug access programmes in the late 1990s and early 2000s. These programmes have the overall aim of making high value branded drugs more affordable and accessible to selected health care purchasers in developing countries with high HIV burdens. Current PPPs operating in Botswana are: a five-year agreement with Boerhinger-Ingelheim to donate Viramune® (nevirapine) for prevention of mother-to-child transmission; an indefinite memorandum of understanding (MOU) with Pfizer to provide Diflucan® (fluconazole) for treatment of two indicated opportunistic fungal infections (cryptococcal meningitis and oesophageal candidiasis); and discounted pricing arrangements with five pharmaceutical companies, which are participants in the UN-supported Accelerating Access Initiative.

The Government of Botswana also has a very significant partnership to address HIV/AIDS in the form of the African Comprehensive HIV/AIDS Partnerships (ACHAP). This was initiated by Merck & Co, Inc., and the Bill & Melinda Gates Foundation with the Government of Botswana in 2000. The offer of donation of Stocrin®/efavirenz and Crixivan®/indinavir sulfate, two anti-retroviral (ARV) drugs, was included in the ACHAP agreement by Merck.

Findings and conclusions

■ Products supplied through the HIV/AIDS related donation partnerships and discount arrangements are greatly valued by the Government of Botswana and are in line with national priorities and policies. There is strong compliance with WHO guidelines for drug donations and discounted single source offers. It is clear that decisions about drug selection are made without company involvement. However, the presence of ACHAP, and Merck's offer of one of the MOH's selected first line ARVs, contributed to the government's confidence to develop plans for a national ARV therapy programme in 2001.

■ An important feature of the implementation of the drug access partnerships in Botswana is their full integration into the national drug supply and management system. This demonstrates a commitment by companies to tailor their accountability requirements to country context and capacity. Measures requested by companies to support effective use and accountability are widely viewed as reasonable. Indeed, some reporting measures, though perceived as somewhat laborious in the context of very limited IT access at facility level, are also contributing to 'raising the bar' in terms of standards for national drug security and management systems.

■ The partnerships have certainly contributed to increased access to HIV/AIDS drugs, in terms of coverage and take-up rates of treatment programmes for anti-retroviral therapy, opportunistic infections and prevention of mother-to-child transmission of HIV. In line with National Health Policy, all services are available free of charge to Batswana (citizens of Botswana). However, the socio-economic distribution of patients accessing treatment is not known. Some interviewees at facility level were concerned about unequal access for poorer people, due to indirect costs. While this issue is not directly linked with the drug access programmes, it does raise serious questions for health services in general about the overall strategy for resource allocation, including drugs, and the need to develop ways to ensure inclusion of the poorest and marginalised, and for measuring and disaggregating data on treatment access. A monitoring system that includes assessment of socio economic status would support the design of appropriate strategies to tackle any inequities.

■ The lack of a centralized overview function in government for the drug access partnerships may mean that opportunities are missed in terms of developing a consistent approach over time to price and timeline negotiations or conditionalities. With respect to the donations, there was some perception that: 'If you get something for free, then don't stir the water'. There was little evidence of a continuous proactive approach for further price reductions for antiretroviral drugs following initial negotiations in 2001. Drug donation or discount arrangements should be viewed more as a contract with both partners actively negotiating and agreeing terms, on a regular basis. This approach would certainly be in line with the government's good practice in tendering and contracting policies and procedures.

■ It is important for all partners to have shared understanding about the nature of the partnerships, the value of donated inputs, the time periods and sustainability questions. It is striking that very few interviewees were inclined to put a value on donated products, which for the Stocrin® donation by Merck is very significant. Whilst clearly valued as a saving for the system, all in-kind contributions appeared to be excluded in financial terms for budgetary purposes. This has serious implications for sustainability planning. Short-term gains need to be weighed against the longer term risks of donation agreements, in terms of sustainability and drug choice if the donation were to cease in the future.

■ A key policy question is the willingness of pharmaceutical companies to extend donation and discount offers to the private sector, as part of national public-private partnerships with providers, as a contribution to scaling up treatment strategies. There are various proposals under review suggesting the use of public sector finance to pay providers through a managed care or franchise scheme, with appropriate patient and drug monitoring. These proposals represent a significant opportunity for an innovative model that brings together national and international PPPs to improve access to medicines, not only for HIV/AIDS but other essential health services. There are initial positive signs that some companies may be willing to extend offers in Botswana should such a scheme be approved for anti-retroviral treatment.

■ Since the first agreement with the Government of Botswana in 2000, companies are developing their involvement – to greater and lesser extent – as new and valued development partners in Botswana. A range of models involving industry partners is in place, from products only to products

plus provision of technical and financial support. For example, for the provision of Diflucan® and Viramune®, very few, if any additional inputs are needed to ensure effective use and accountability in a system with substantial existing capacity, such as that in Botswana. ACHAP provides an example of an innovative system-strengthening model, making contributions to HIV/AIDS programming in line with government priorities.

- Discount and donation programmes may have longer-term implications in terms of value for money and market impact. Discount agreements can contribute to a downward pressure on prices (in markets where competitor products are also available). However, while donation programmes are greatly valued by recipients, their long term or indirect effects can rule out local competition, particularly if the recipient perceives an obligation to use a sole source. The status of fluconazole provides an interesting case in point. The patent has expired, but generic versions are not registered. Therefore, while the public sector benefits from Diflucan® donations, fluconazole is not procured in cheaper generic form by the private sector, including by insurance providers who are purchasing drugs and treatment services on behalf of public sector insured employees.

- Botswana has registered and uses only branded products for HIV/AIDS treatment at present. The government wishes to obtain 'the right drugs at the right price', and has concerns about generic quality and reliability of supply. However, some interviewees held perceptions that could limit Botswana's range of choices in the medium and longer term. First, in the context of intellectual property rights, some interviewees expressed anxiety about industry's response to the government's introduction of public health flexibilities provided for by the WTO's intellectual property rights agreement into domestic legislation. However, it should be noted that no pharmaceutical companies currently hold patents in Botswana. Second, there are some perceptions that the discount agreements with R&D companies might mean that the country is restricted to use of their branded products only, although this in fact is not the case. It is important that shared understanding is developed by industry, government and other partners on these potentially sensitive issues.

- Sourcing less expensive generics is not seen as a priority, as for now the government can afford the branded products and has confidence in their quality standards. Scale-up has also been lower and slower than expected, hence expenditure on drugs lower than budgeted. With a free public sector service, and a small private market, there is also limited public pressure to reduce cost to consumers. For as long as the Merck donation continues, the total cost of the two first line regimens per year is roughly equivalent to the average price for developing countries quoted by WHO in its 3 by 5 review in June 2004.

- However, in the medium and longer term, generics could contribute to greater coverage and adherence (using triple therapy fixed dose combinations currently only available from generic companies). This is particularly in the context of ARV scale-up plans and sustainability, and should Merck's donation cease. Officials are ensuring that all options will be open to government, in terms of maximizing their leverage in competitive procurement and/or bilateral negotiations for better prices. However, regarding Botswana's intellectual property rights legislation, there is some perception that government has been slow to move on these issues, and that intra-governmental coordination has not been as strong as needed.

- Ongoing efforts are needed to monitor and negotiate appropriate medical education and patient information material, sometimes offered in the context of donation and discount arrangements. For example, the use of the brand name only in the DPP's patient information materials is not in line with the government's national drug policy (which mandates use of generic name in patient and prescribing information). Should the donation cease and/or the government make alternative plans for procuring the drug, any brand preference among consumers or prescribers could compromise prospects for generic substitution.

1. Study purpose, background and methodology

Introduction and background

This study of public private partnerships for improving access to pharmaceuticals is one of a series commissioned in 2003–2004 by IPPPH, and funded by the UK Department for International Development. In addition to Botswana, country studies were carried out in Uganda, Zambia and Sri Lanka. In Botswana, the study looked at PPPs to improve access to HIV/AIDS-related conditions, in contrast to the other countries, where the study also looked at PPPs that address tropical diseases.

HIV/AIDS is having a major impact on health, poverty reduction and development objectives across sub-Saharan Africa, and in Botswana, as described in section 2: Health and HIV/AIDS in Botswana. As the severity of the epidemic hit home in the late 1990s, a broad consensus has developed on both the need and the technical feasibility of providing HIV treatment, based on anti-retroviral therapy, to people with AIDS in developing countries. This is coupled with new mechanisms, such as the Global Fund to Fight AIDS, TB and Malaria, to raise the additional finance needed, and drug price reductions through market development, generic competition and branded product PPPs.

Several of the major research based pharmaceutical companies initiated donation and discounted drug access programmes in the late 1990s/early 2000s. The first was the UNAIDS sponsored Drug Access Initiative, described in detail in the Uganda study report in this series, and which was followed by the Accelerating Access Initiative (AAI). These programmes have the overall aim of making high value branded drugs more affordable and accessible to selected health care purchasers in developing countries with high HIV burdens.

Seven companies now participate in the AAI, which was established in May 2000 to help increase access to HIV/AIDS care and treatment in developing countries, including in high burden middle-income nations. It is now a partnership of five UN organisations (UNAIDS, WHO, UNICEF, UN Population Fund, and the World Bank), and the research-based companies: Abbott Laboratories, Boehringer-Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, F. Hoffmann La-Roche, Gilead Sciences and Merck & Co., Inc.

It should be noted that, as in Botswana, AAI increasingly provides a framework and guiding principles for bilateral company-government negotiations, without the direct involvement of UN organisations. Several companies manage drug donation as well as discounted access programmes, such as Boehringer-Ingelheim's Viramune® Donation Programme. Non-AAI companies, such as Pfizer, have also introduced drug access programmes.

Botswana qualifies for – and participates in – several of these major international drug donation and discount programmes offered by pharmaceutical companies. Current programmes operating in Botswana are:

- the five-year agreement with Boehringer-Ingelheim to donate Viramune® (nevirapine) for prevention of mother-to-child transmission;
- an indefinite MOU with Pfizer to provide Diflucan® (fluconazole) for treatment of two indicated opportunistic fungal infections (oesophageal candidiasis, OC and cryptococcal meningitis, CM);
- and discounted pricing arrangements with five pharmaceutical companies, who are participants in the Accelerating Access Initiative.

All the programmes specify 'public sector' distribution, which is defined to include four NGO and corporation facilities supported by government (run by mission and mining sectors).

The Government of Botswana also has a very significant development partnership in the form of

ACHAP (the African Comprehensive HIV/AIDS Partnerships). This was initiated by Merck & Co Inc., and the Bill & Melinda Gates Foundation with the Government of Botswana in July 2000. The offer of donated Stocrin® and Crixivan® were included in the agreement by the Merck Corporation for use as antiretroviral (ARV) drugs in the treatment of HIV/AIDS, should the government decide to develop a treatment programme during ACHAP's lifetime. The five-year public private partnership was endowed with a sum of US$ 100 million, contributed equally by Merck and the Gates Foundation. ACHAP is involved in a wide range of initiatives for prevention, care and treatment of HIV/AIDS in Botswana, including support to the ARV programme. The drug donation component of the agreement is one aspect of the broader commitment by The Merck Company Foundation/Merck & Co., Inc, to addressing the HIV/AIDS epidemic in Botswana.

As described in Section III, the global market for anti-retroviral drugs for treating HIV/AIDS is growing rapidly in size and complexity. As the international community and national governments have mobilized additional finance for treatment provision and drug procurement, the supply side has responded with increasingly competitive production, development of generic versions and substantial reductions in price. Countries are faced with very complex choices, as they seek the best deals in terms of trade-offs between price, formulation, reliability of supply and quality. The changing intellectual property environment, linked to WTO membership and the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), is also likely to have a major direct or indirect influence on drug procurement policies. This study reviews Botswana's engagement with drug donation and discount programmes within this wider policy and market context.

Study purpose and methodology

Study terms of reference are appended in Annex 1. In brief, the study's purpose was to assess the health and health systems impact in Botswana of public-private partnerships for improving access to pharmaceuticals through drug donation and discount programmes in relation to treatment of HIV/AIDS and opportunistic infections. Specifically, the study set out to examine issues of ownership, integration, co-ordination, implementation and impact, with particular focus on the unique strengths and challenges of these access PPPs, as distinct from other health sector programmes where drugs are competitively procured. The key research question concerns the degree to which the involvement of multinational research and development-based pharmaceutical companies, as partners in supplying free or discounted drugs, facilitates drug availability and access by the poor.

Key issues for examination included:

- the relationship between government priorities and policy processes, and the PPP's objectives
- the roles of the various partners, including government, private sector and others, in decision making, accountability arrangements and operational aspects of programme management and implementation
- the extent of the PPP's integration with national disease programmes and broader health care planning and service delivery
- programme coordination and links with other PPPs and government health programmes
- programme impact on health and poverty, in terms of coverage of vulnerable groups, and with respect to tackling disadvantage due to gender, socio-economic and other inequalities
- issues for sustainability and scaling up, and impact on broader health system capacity
- identification of any benefits, challenges and lessons learned arising from the involvement of the private sector in drug access programmes, that might be of value to both public and private sector partners.

The four country studies and other project activities were overseen by a Study Advisory Committee, which supported the initial pilot study in Uganda, and reviewed the three further studies, to ensure a coherent and consistent approach. The Botswana study is based on an adapted version of the methodology that was developed and used for the other three country studies. This methodology was reviewed and approved by Botswana MOH's Health Research Development Committee. It was a rapid and largely qualitative study making use of document review and semi-structured interviews, based on a common set of issues, with key informants at national and district levels.

The country fieldwork was undertaken in Botswana over a period of two weeks in May 2004, by a team of four. Team members were: Otsetswe Mosime, a

management consultant based with Atos KPMG Consulting in Gaborone; Dr Joyce Kgatlwane, an MOH official with Botswana's Essential Drugs Action Programme; Dr Ilavenil Ramiah, a research fellow with the Harvard School of Public Health, USA; and Nel Druce (team leader), based with the Institute for Health Sector Development in the UK. All members of the team are independent of IPPPH and the pharmaceutical industry. One team member, Dr Ramiah, was concurrently contracted by ACHAP to produce a fully independent study of ACHAP-government relationships.

A range of government, development partner, private sector and other representatives took part in over 50 interviews. The study included visits to eight district level public health facilities providing HIV/AIDS related services, including two government-supported hospitals managed by the corporate mining sector (Debswana) and a faith based organization. The districts included: Francistown, Gaborone, Gantsi, Jwaneng, Kanye, Mahalapye and Maun. They were selected to represent regional and socio-economic diversity in the country, and a range of facility types (primary, district and referral levels). However, at district level, interviews were primarily with MOH facility staff. Given tight time constraints, it was not possible to gain official approval to meet with the District Health Team and staff based at clinics under the Ministry of Local Government. However, the team is confident that relevant officials at national level were able to cover any information gaps, particularly as the Central Medical Stores manages drug supply for facilities under the Ministry for Local Government, as well as the MOH.

Acknowledgements

The study team is highly appreciative of the support it received for carrying out this study from colleagues in the Government of Botswana. In particular, the interest and willingness of the MOH is acknowledged, especially in assigning Dr Joyce Kgatlwane as MOH counterpart and full member of the team. Her experience, contributions and insights were immensely valuable. The team is much indebted to all interviewees at national and district level, and among development partners and other stakeholders, for their time, interest and sharing of views. We hope that this report will be of interest to them, as well as international readers.

2. Health and HIV/AIDS in Botswana: Context, challenges and responses

Country context[1]

Botswana, formerly a British protectorate, gained its independence from the UK in 1966. Since then, it has been governed under a peaceful parliamentary system, currently led by President Festus Mogae. At independence, the landlocked country in Southern Africa was one of the poorest in the world but during the last 20-30 years, it has enjoyed one of the world's highest growth rates, thereby transforming itself into a middle-income country. In 2002, per capita GDP was US$ 9,500 (at purchasing power parity) and growing at 6%. This economic success is fuelled by diamonds that, along with other minerals, currently account for more than a third of GDP and 90% of export earnings. Other economic sectors include tourism, subsistence farming and cattle rearing. Like other countries heavily dependent on mineral resources, there are significant problems of unemployment and poverty. Unemployment is officially 21% but unofficial estimates place it at closer to 40%. Income disparity is quite high, with 60% of the population earning less than US$ 2 a day. Long-term prospects are also overshadowed by the prospects of a levelling off in diamond mining production (Central Intelligence Agency).

In 2001, the population was 1.6 million of which just under half were living in urban areas. Life expectancy at birth rose to over 60 before the impact of HIV reduced it to 39 in 2001, with infant mortality at 58 per 1,000 live births (Sackey and Raparla 2001). The population is nonetheless well educated and has widespread access to water. The capital, Gaborone, is one of ten administrative districts of which four are town councils. The main ethnic group is the Tswana who make up nearly four fifths of the population, with the Kalanga, Basarwa and others making up the remainder.

[1] This section draws extensively on *HIV and Health Systems: Botswana*, by Louisiana Lush and Ernest Darkoh, unpublished paper, 2003.

Table 1. Demographic indicators for Botswana

	2001
Population mid-year (millions)	1.6
Average annual growth rate (%)	1.7
Life expectancy at birth (years)	39
Infant mortality (per 1,000 live births)	58
Child malnutrition (% of children under five)	17
Primary education completion rate (% female)	95.3

Source: World Bank 2003

Botswana's health system

The Botswana public health system is under the authority of the Ministry of Health (MOH) and the Ministry of Local Government (MoLG), both guided by the National Health Policy (United Nations Development Programme 2000). The health system is oriented towards primary health care to delivery maximum social benefit from resources. Difficulties of defining roles and responsibilities are acknowledged in the policy (United Nations Development Programme 2000).

In recent years, health expenditure has risen markedly to 6% of GDP in 2000, of which nearly two-thirds is public sector (World Bank). Total health expenditure per person in 2001 was US$ 190. Around 90% of the population has access to health care (defined as within 15 km of a facility) although access remains a problem – particularly for referral services – since a large sector of the population lives in remote districts.

The Ministry of Health is responsible for determining the National Health Policy and has direct authority over referral, district and primary hospital services. In addition, it supports a number of specialist programmes, of which the AIDS/STD unit (ASU), the epidemiology (including tuberculosis), health planning, national health research, maternal and child/family planning, and manpower units are all key for HIV/AIDS policy.

The Ministry of Local Government runs basic health services, including primary health care clinics, health posts and other community services within the district health system. MoLG is also responsible for social welfare services and councils have specific responsibility for health promotion, basic curative services, referrals to higher health care levels, counselling, family health and social welfare. They also manage the district health teams that include a communicable diseases officer focusing on HIV/AIDS and tuberculosis.

District, city and town councils plan, provide and evaluate basic health services in consultation with the MOH, in accordance with the National Health Policy and guidelines. The system is expected to function coherently and to link to social services. The main forum for consultation between the various authorities is the Primary Health Care Coordinating Committee which meets quarterly, chaired by the Deputy Permanent Secretary for Health.

There are two referral hospitals in the country (Princess Marina Hospital in Gaborone and Nyangabwe in Francistown) with an additional specialist psychiatric hospital and one private hospital (Gaborone Private Hospital). There are 12 district hospitals, of which six are private – three mine and three mission hospitals. There are 16 primary hospitals – staffed by doctors, pharmacy technicians, laboratory technicians, radiographers and nurses. In addition, in 2000, Botswana had 222 clinics, 330 health posts and 740 mobile stops country wide .

In 1998, 14,200 people were employed in the health sector , absorbing 53% of the health budget although in all areas of the health system, personnel accounted for a shrinking proportion of recurrent spending through the 1990s. Scarcity of trained health workers is recognised as the main constraint on improving equity and levels of health care in Botswana. Despite improvements in the doctor or nurse-patient ratios since the 1980s, skills scarcity persists in a number of crucial areas especially at primary health care level .

Although Botswana's primary health care system is relatively well developed, its main focus has been preventive care with varying supplies of drugs and expertise in facilities. Partly in compensation, family welfare educators have been recruited within communities and receive basic preventive care training to work in the community. Frequently, despite very little capacity for curative care, they have moved to clinics, to cover for absent professional nurses. In 1998, a study found that 14% of clinics did not have posts for staff with professional qualifications and 17% had not had a nurse for three months . Nurse practitioners and community nurses – with post-basic training – tended not to be adequately deployed at primary health care levels and may not have the capacity needed to coordinate HIV/STI and tuberculosis services (as required) (*ibid*).

Table 2. Numbers of health personnel 1987-97

	1987	1992	1997	% increase 1987–1997
Doctors	166	316	424	155%
Nurses	1946	3057	4130	112%
Family welfare educators	670	692	749	12%

Source: UNDP 2000; health statistics

To summarize, in Botswana, compared to elsewhere in sub-Saharan Africa, a relatively large proportion of the population has quite good access to health care. Although the population has been growing rapidly, relative economic security has meant that health care has expanded in line with increases in numbers needing treatment. Nevertheless, in Botswana as in many other countries, HIV/AIDS impacts heavily on health services and poses particular challenges (see later section).

National drugs policy and management

The Botswana National Drug Policy (BNDP), first developed in 1999, is founded on the principles of the National Health Policy. The National Development Plan 9 (NDP9) identified its effective implementation as a priority. The BNDP provides a framework for incorporation of the objectives of the pharmaceutical sector into national health policy, service structure and operations in order to ensure a quality service, system efficiency and cost containment.

The policy's overall aim is to make drugs of acceptable safety, efficacy and quality, available and affordable to all those who need them, and to promote their rational use by prescribers, dispensers and consumers. The policy also promotes preventive care, informed decision making and overall individual responsibility for health, and contributes to the control of drug use, misuse and abuse.

This is achieved through ensuring adequate resources for medicines and medical supplies, along with improvements in procurement and distribution systems; developing the National Drug Formulary and the Essential Drugs List, updating the treatment guidelines, reviewing the Drugs and Related Substances Act of 1992 and Regulations of 1993; building pharmaceutical infrastructure such as the National Quality Control Laboratory; establishing the Botswana Essential Drugs Action Programme; building human resource capacity and strengthening the Drugs and Regulatory Unit as a semi-autonomous body.

The policy's broader economic and developmental objectives are to promote the lowering of drug costs in both the private and public sectors; to create a conducive environment for partnership between governmental and non-governmental providers in the pharmaceutical sector by means of an appropriate regulatory and administrative framework; to optimize the use of scarce resources and facilitate cross fertilization of ideas through cooperation with international and regional agencies; and to promote, support and encourage the development of local pharmaceutical industry and the production and distribution of essential drugs and raw materials.

Legislation, regulation and quality assurance

The Health Professional Act guides professional practice in Botswana. Recently, a Health Professional Council was established that is responsible for registering health professionals. Prior to that, registration was done by the Director of Health Services with the assistance of subcommittees that were responsible for examining, for example, pharmacists and pharmacy technicians.

The Drugs and Related Substances Act of 1992 and Regulations of 1993 established the Drugs Advisory Board, which is responsible for registration of the drugs. The Drugs Regulatory Unit (DRU) under the Ministry of Health serves as the secretariat of this board and also as the body for implementing the Drugs and Related Substances Act. It is responsible for assuring safety, quality and effective of medicines in both the public and private sectors through control of manufacture, import, export, distribution, promotion, information and clinical trials. It is also responsible for ensuring that only registered drugs enter the country; inspection of premises and post marketing surveillance and reporting of adverse effects. The DRU also actively participates in the process of harmonization of medicines regulatory issues within the Southern Africa Development Community (SADC).

Selection and rational use of medicines

Botswana has adopted the WHO's Essential Drug concept, reflected in the BNDP's essential drugs list, use of standard treatment guidelines and use of generic drug names. For example, the policy states that all drugs in the public sector should be procured by generic name only. The generic name should be used in training, in prescriptions, and patient labeling and information. Botswana has also adapted for national use the Inter-Agency Guidelines for Drug Donations, published by WHO (see Annex 4).

The selection of drugs and medical supplies is done through the National Standing Committee On Drugs (NASCOD). Various subcommittees are responsible for reviewing and developing treatment protocols and regimens for approval by NASCOD. These include the Malaria Reference Group, Diflucan® Partnership Working Group, HIV/AIDS Clinical Advisory Committee, PMTCT National Committee/PMTCT Technical Advisory Committee, and IPT Committee. Some districts and facilities have developed pharmacy and therapeutic Committees to advise on the selection and management of medicines at facility level.

Roles and responsibilities in public sector medicines supply

The procurement of drugs and medical supplies used in public sector health facilities under the Ministry of Local Government and Ministry of Health is done through government owned Central Medical Stores (CMS). Except where separate agreements are in place, Central Medical Stores usually procures drugs and medical supplies through a local, regional and international tendering system and the Public Procurement and Assets Disposal Board (PPADB) oversees the tendering process. Discount and donation arrangements must be approved by the Board. CMS also procures less-used drugs and medical supplies off tender.

Mission and mine hospitals, private hospitals, private practitioners and community pharmacies procure drugs and medical supplies directly from suppliers. However, the mission and mine hospitals obtain discounted and donated drugs, as well

as other essential drugs for public health, through CMS.

CMS uses a computerized system to record the quantities of drugs received, quantities distributed and where they were distributed to, and the price in addition to other information. Botswana, in contrast to other countries in the region, has an effective and long established 'pull' system of drug ordering to health post level, where pharmacy staff are responsible for ordering required amounts according to utilization.

Drug procurement in the private sector

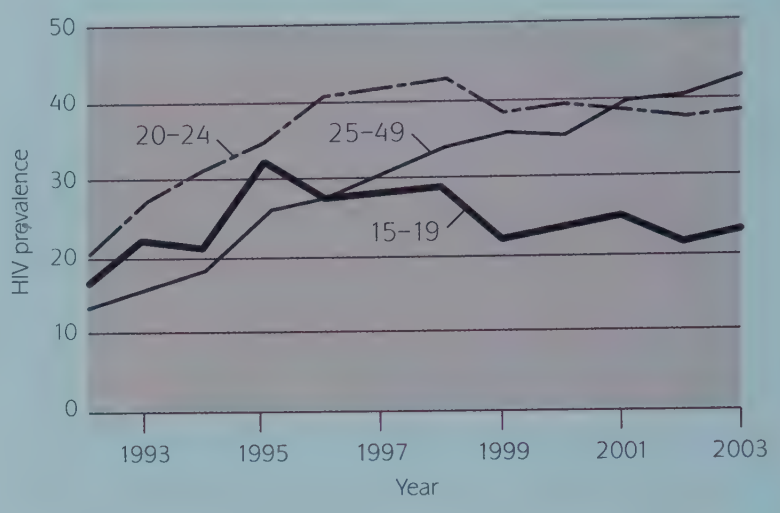
The private sector is covered by the national legislative framework described above and is viewed as being reasonably well in line with the regulation. Providers (or insurance scheme managers) negotiate and procure the drugs directly from Botswana based wholesalers, who deal mainly with South African suppliers. Private sector facilities, including those providing medical services to public sector insured employees, currently do not benefit from the donation programmes. In the private sector, insured patients contribute 10% towards consultation, investigational procedures and drugs and medical supplies. The medical aid schemes and the pharmaceutical companies have made an agreement with the local wholesalers that where ARVs are concerned, the mark up should not be more than 10%.

The HIV/AIDS epidemic

Botswana currently has one of the highest rates of HIV in the world. In 2003, overall prevalence among 15-49 year olds in Botswana was at an estimated 37.4% with a range of up to 52.2% prevalence in Selebi Phikwe district. In over a third of the country, prevalence exceeded 40% (Botswana 2003 2nd Generation HIV Surveillance Report). In 2002, the government estimated that about 258,000 Batswana were living with HIV/AIDS and declared it a national emergency .

The first case of AIDS in Botswana was reported in 1985. Subsequently, the rates of HIV in Botswana rose from around 5% in 1990, when sentinel surveillance data started to be collected nationally . In 2001, contrary to initial projections of a plateau at around 25% prevalence, urban antenatal surveillance sites reported a median prevalence of 44.9%, with minimum 39.1% and maximum 55.8% . In rural areas, figures were slightly lower. In all districts, more than a fifth of pregnant women were infected and in some more than a half. While preliminary evidence from younger age groups suggests a slight decline in incidence and prevalence from 2001–2003, incidence continues to be high among all age groups, especially between 25–29 years. Data on other population groups are limited and estimates of national prevalence rely on antenatal surveillance systems.

Trends in HIV prevalence among pregnant women by age group



Source: Botswana 2003 Second Generation HIV Surveillance Report

The determinants of this epidemic are the interlinked and fundamental elements of the Botswana culture and social structure. The National Strategic Framework cites four categories of determinant: stigma and denial; socio-cultural determinants; socio-economic determinants; and demographic mobility (National AIDS Coordinating Agency 2003). The majority of those infected in Botswana continue to be ignorant of their status, and continue to infect their sexual partners. Those with the disease suffer severe stigma and few talk openly about their experiences. Women are particularly vulnerable in a culture which subordinates their needs to those of men and in which they have little economic independence. Society at large tends to still accept men having multiple partners and places women under great pressure when trying to protect themselves by changing their own and their partners' sexual practices. Alcohol consumption, especially among the young, is high and has been shown to increase levels of casual, unprotected sex.

Socio-economic factors involved in the spread of HIV in Botswana can be represented by a cycle of real or perceived needs and exploitation. People with high levels of disposable income are at risk

since they can exploit situations of relative inequality and exert unfair advantage in the pursuit of sex. Poorer people, however, are also vulnerable since they may adopt high-risk survival strategies in order to meet their daily needs. This infection cycle also has gender and generational elements since it is often richer, older men providing support to poorer, younger women in return for sexual favours (National AIDS Coordinating Agency 2003).

In addition, the rapid economic growth over the last 20 years in Botswana has taken place in a highly mobile population. Traditionally, the Batswana often migrated in search of fertile agricultural land. This mobility grew during the colonial era when men migrated to South Africa in search of jobs. More recently, the population has drifted from rural to urban areas and traditional social and cultural systems have been eroded. Botswana is also a landlocked country at the centre of the Southern African region which has been particularly hard hit by the epidemic – good quality transport networks between countries like Zimbabwe, South Africa, Namibia and Zambia have contributed to the spread of the epidemic along routes and among transport workers and their sexual partners.

Demographic and economic impact of HIV/AIDS

The demographic impact of HIV/AIDS can be seen in the changing structure of the population and its growth rate. Mortality has risen in all age groups – if nothing is done, a third of the current population will die within 10 years and there will be increasing proportions of young and old with respect to productive adults. Life expectancy in 1999 was 33.5 years, as opposed to a projected 68.8 in the absence of AIDS (United Nations Development Programme 2000), and it has been estimated that by 2010, life expectancy could be as low as 29 years. By 2015, AIDS deaths will also more than double the national death rate. In 2001, the World Bank projected that by 2015, the population of Botswana would be 1.7 million – some 67% lower than it would have been in the absence of AIDS.

The macro-economic and social impact of HIV/AIDS acts through its effect on the productive labour force and is greater than other diseases since the sexually active population it so disproportionately affects is also the working age population. The return on government investments to promote foreign direct investment, diversify the economy and create employment will decline during the next 5-10 years as the adult population shrinks, taking with it crucial skills and experience (National AIDS Coordinating Agency 2003).

Apart from directly reducing the number of working people, AIDS will also change the dynamics of skill accumulation in the labour market, making the labour force younger and less skilled or experienced. However, because the Botswana labour force is largely unskilled at the moment, this impact appears lower than might be expected although it will hinder efforts to raise productivity (Sackey and Raparla 2001). AIDS will also affect savings and investment relations as expenditure by households and governments will reduce the amount of capital. Botswana has succeeded historically in building up revenues from diamonds to act as a buffer in periods of lower savings – between 1987 and 1997, gross fixed capital formation averaged 28% of GDP. AIDS related expenditure will erode this safety net.

The epidemic will also increase poverty and human suffering within households and communities – nearly all households in Botswana have now experienced the illness and death of a family member and the number of AIDS orphans was 78,000 in 2002 – and predicted to rise to over a fifth of all children by 2010 (National AIDS Coordinating Agency 2003). An analysis by the Botswana Institute for Development Policy Analysis showed that HIV/AIDS will cause a decrease of 8–10% in household per capita income between 2000 and 2010 (Botswana Insitute of Development Policy Analysis 2000). HIV/AIDS forces households to spend more on health and lose income with many being pushed into poverty as a result. Poor households will be disproportionately affected by the costs of AIDS care and funerals as well as the loss of productive family members (Botswana Insitute of Development Policy Analysis 2000).

The largest economic impact has been and will be felt in public expenditure, particularly in the health and education sectors. AIDS has weakened the government's capacity to deliver essential services to sustain human development – by 2003, Botswana had slipped down the UNDP Human Development Index rankings to 125, from 71 in 1996, out of a total of 171 countries (National AIDS Coordinating Agency 2003). While Botswana is lucky in having a cushion of high levels of foreign exchange reserves, erosion of these could further hinder local economic investment.

High levels of morbidity and mortality among teachers threaten to reduce the number of staffed classrooms and the quality of teaching – as well as requiring the government to train over 20% more teachers than without AIDS (Sackey and Raparla 2001). As more children are either infected, caring for sick relatives or supporting their family, school enrolments are expected to decline. Those at school may be traumatised and less able to learn.

AIDS impact on health services

An increasing proportion of public and private health resources are devoted to the care and treatment of HIV/AIDS patients – who have longer than average hospital stays (nine days as opposed to five for non-HIV patients) and can displace other patients. Identifying the impact of HIV/AIDS on hospitals is complicated by under-reporting of HIV-positive patients but in 2000, UNDP published a report showing dramatic rises in hospital death rates among neonates and the 15–44 age group. Confirmed AIDS deaths rose 300% between 1992 and 1997. By 1996, AIDS was the second commonest cause of neo-natal hospital deaths (United Nations Development Programme 2000). Most hospitals reported rising occupancy rates and overcrowding as well as long hospital stays. Over two-thirds of hospitals reported inadequate staff for increased patient loads and staff burnout.

A projection of acute hospital bed day requirements was made in 1999 showing a rise from 323,400 bed days in 1999 to 616,800 in 2010 under a low estimate, or 1.7 million in 2010 under a high estimate (United Nations Development Programme 2000). Such rises have the potential to massively increase hospital costs – with and without antiretrovirals. Hospital costs include simple 'bed day' management as well as drugs, blood and diagnostic tests. In 2000, expenditure for HIV/AIDS related hospital care was expected to double by 2010 (United Nations Development Programme 2000).

The impact of HIV/AIDS on primary health care services was also assessed in 2000 – both in terms of increased volume of patients and a different range of complaints. In Botswana, anecdotal evidence suggests that HIV/AIDS patient load has increased substantially and that the majority of patients seen are in an advanced stage of disease – in fact often bypassing primary care and going directly to hospitals.

Policy and programme responses to HIV/AIDS

Overall policy framework and political leadership

Prior to 1990, when little was known about the spread of the epidemic, the focus of HIV/AIDS activities was on screening blood to eliminate blood transfusion risks. From 1989–1997, under the first Medium Term Plan, other preventive activities, including information campaigns, were initiated but the national response was still fairly narrowly focussed. In 1993, the government adopted the Botswana National Policy on AIDS and revised it in 1998 (National AIDS Coordinating Agency 2003).

Subsequently the health response expanded to include comprehensive education and prevention programmes as well as the initiation of care and treatment, including the provision of anti-retroviral therapy (ART), beginning in January 2002. In addition, the second Medium Term Plan (MTP II) which covered the period from 1997–2002, established a multisectoral response which aimed to reduce HIV transmission and mitigate the impact of AIDS at all levels of society.

The MOH remains the lead policy sector in policy and programme development for HIV/AIDS and the National AIDS Council (NAC) is responsible for coordinating a multisectoral response to HIV/AIDS. Chaired by the President of the Republic of Botswana, the NAC also has representation from the MoLG, Office of the President, Ministry of Finance and Development Planning, other ministries, business and civil society. At district level, District Multisectoral AIDS Committees (DMSAC) have been established in all districts and sub-districts.

High-level political support for the AIDS effort is a new feature of the Botswana response. President Mogae, convinced of the severity of the emergency by a number of economic and demographic studies, committed personally to pushing the AIDS programme to a much higher level of financing and service delivery. In addition to conceptualising and mandating the introduction of antiretroviral therapy, the President has significantly increased both the profile and level of debate on HIV/AIDS.

The highest policy making body regarding HIV/AIDS is the National AIDS Council (NAC). Leadership from all sectors in the country are repre-

sented in the NAC which is chaired by the President. The National AIDS Coordinating Agency (NACA) acts as secretariat to the NAC and falls under the Office of the President. In 2000, it was given responsibility for mobilising and coordinating the multisectoral national response to the epidemic. The NACA administers a workplan against which each sector reports progress. At a minimum, meetings are held quarterly with ad-hoc meetings arranged for discussion and resolution of special high priority issues. The personal intervention of the President ensures alignment and maintains performance pressure and a sense of priority across a broad range of stakeholders.

In 2003, the National Strategic Framework was published in response to criticisms of the Medium Term Plan (MTP II), which was considered to lack formal objectives, implementation structures and processes or monitoring indicators . The Framework was developed through a highly consultative Strategic Planning Process that brought together stakeholders at all levels and in all sectors of society. Key innovations include a greater management focus, clear identification and allocation of implementation responsibility, mainstreaming of HIV/AIDS in district and urban development plans, provision of indicative resource requirements and clear, measurable impact indicators across objectives in all intervention areas.

The Framework's purpose is to inform both the public and implementing agencies with a clear vision of how it intends to eliminate HIV incidence in Botswana and reduce its impact by 2016. It includes basic minimum packages for each level of the health system and a monitoring plan, including the establishment of the Botswana HIV/AIDS information management system to guide implementation of the national response (Masupu, Gboun et al. 2002).

There are five key goals identified in the Framework – prevention of HIV infection, provision of care and support, strengthened management of the national response, psycho-social and economic impact mitigation, and provision of a strengthened legal and ethical environment – all of which contain some element for which the health system is responsible. The Ministry of Health is charged with a wide range of interventions to prevent, manage and treat HIV/AIDS (see below). It is also respon-

Table 3. Structures for the Botswana national multisectoral HIV response

Organization	Role
National AIDS Council (NAC)	Established 1995. Membership government, NGO, private sector and PLWHA. Chaired by the President. Overall oversight of implementation of national HIV/AIDS response. Goal to achieve AIDS-free generation by 2016.
Parliamentary Select Committee on HIV/AIDS (PSC)	Established 1998. Goal to ensure that HIV/AIDS remains on economic and political agenda of the government. Meets twice a year, undertakes publicity campaigns and fund raising.
National AIDS Coordinating Agency (NACA)	Established 1999 initially under MOH. In 2002 shifted to the Office of the President under the Ministry of the State President. Acts as secretariat to the NAC. Specific responsibilities: policy development; coordination and facilitation of implementation; monitoring and evaluation of expanded response; mobilisation of resources.
Sector Committees	Several ministries have established HIV/AIDS committees to guide and develop sectoral responses. Challenges include limited high level support and participation, lack of clear mandate, funding constraints and lack of HIV/AIDS coordinators.
AIDS/STI Unit (ASU), Ministry of Health	Established 1992 with the merging of AIDS and STI units. Located in the Department of Primary Health Care Services. Seven technical subunits: clinical management, STIs, home-based care, counselling, IEC, surveillance and research, and NGO coordination. Currently too low ranking – likely to be elevated to department reporting directly to Director of Health Services.
AIDS Coordination Unit (ACU), Ministry of Local Government	Established 2001. Acts as the interface between the districts and the central level. Provides technical assistance to the districts.
District Multisectoral AIDS Committees (DMSACs)	Established 2002/03 in all districts and most sub-districts. Membership includes Heads of Departments, District Councils, NGOs, traditional authorities, the Land Board, and members of parliament. Participation is not mandatory and there are weak implementation mechanisms. No legal responsibility or accountability for performance.

Source: Masupu, Gboum et al. 2002; National AIDS Coordinating Agency 2003

Table 4. Goals of National Strategic Framework

Goals and impact indicators	Baseline (%)	Target (%)	
	2001–2002	2006	2009
GOAL 1: PREVENTION OF HIV INFECTION			
% adoption of HIV prevention behaviours of people age 15–49	34	50	50
% reduction of infants born to HIV-infected mothers who are infected at 18 months	38	50	100
% decrease of the average HIV prevalence in transfused blood and blood products	1	100	100
% decrease in HIV incidence among sexually active population	6	50	80
% decrease in STI incidence among sexually active population	2	50	100
GOAL 2: PROVISION OF CARE AND SUPPORT			
% of PLWA on HAART returning to productive life	n/a	100	100
% reduction in the national bed occupancy rates	50–70	25–50	13–30
% reduction in the national crude mortality rate	12.4/1000	12	11
GOAL 3: MANAGEMENT OF THE NATIONAL RESPONSE TO HIV/AIDS			
% increase in the number of sectors, ministries, districts and parastatals implementing the NSF minimum HIV/AIDS response packages	n/a	100	100
% increase in the number of sectors, ministries, districts and parastatals implementing annual planned HIV/AIDS activities at all levels	n/a	100	100
GOAL 4: HIV/AIDS PSYCHO-SOCIAL AND ECONOMIC IMPACT MITIGATION			
% of households with registered orphans receiving care and support for orphans	n/a	100	100
% absenteeism and sickness in government ministries, parastatals and the private sector	n/a	10	5
% reduction of the impact of the epidemic on the economy	n/a	n/a	n/a
GOAL 5: PROVIDE A STRENGTHENED LEGAL AND ETHICAL ENVIRONMENT			
Composite policy index on number of policies on ethical, legal and human rights issues relating to HIV/AIDS in circulation to support the implementation of the NSF	0.25	1.0	1.0
National composite index	0.25	1.0	1.0

Source: Masupu, Gboum et al. 2002; National AIDS Coordinating Agency 2003

sible for surveillance and epidemiological research and provides technical support to the HIV/AIDS programmes of other organisations.

The Ministry of Local Government is the other key Ministry for implementing the Framework through providing care and support to families and orphans affected by HIV/AIDS and ensuring that HIV/AIDS is mainstreamed throughout District Development Plans. As a consequence, it is responsible for coordinating all HIV/AIDS activities at district level. District Multisectoral AIDS Committees (DMSACs) have been established to coordinate the district level response and the village level response is organized through the village development committee (VDC) and the village AIDS committee (VAC). However, it is not currently clear how specific officials, such as district health officers, will balance the expectations of both DMSAC and Ministry of Health plans in their work. This lack of clarity presents a threat to the effective achievement of the Framework's ambitious goals.

Prevention measures

Despite the exemplary political leadership, the country still faces some formidable challenges. The most significant challenge is that most people in Botswana still do not know their status, and prevention programmes to-date do not seem to have

attained the desired impact. Low testing rates, linked with failure to change behaviour, in the context of such a large burden of disease continue to drive unprecedented high incidence rates.

Prevention programmes in Botswana include public education and awareness, education for young people, condom distribution and education, and prevention of mother-to-child transmission. General public awareness has been based on the "ABC"[1] conceptual model of prevention, promoted through advertising billboards and posters throughout the country. To-date, however, little impact has been seen and many people still engage in risky sexual activity. Efforts are being made to target public health messages more effectively (AVERT 2003).

The Youth Health Organisation (YOHO) a youth-run non-government organisation (NGO) in collaboration with the Botswana Ministry of Education has developed HIV/AIDS education materials. The Ministry of Education has also developed a teacher capacity building programme with the UNDP and supported by ACHAP, which aims to improve teachers' knowledge and de-stigmatise HIV/AIDS as well as to break down cultural beliefs about sex and sexuality (AVERT 2003).

A social marketing campaign has successfully marketed both male and female condoms in Botswana and they are widely available. Peer education was conducted through schools, at fairs and festivals and in shopping malls, workplaces and bars. ACHAP, Population Services International (PSI) and the University of Botswana recently undertook a market research campaign to investigate national attitudes towards sex and condom use that indicated considerable unmet need. In response, the government, with assistance from ACHAP, will install 10,500 condom dispensers to provide free condoms to the public (AVERT 2003).

Prevention of mother-to-child transmission has become a priority with the high prevalence among pregnant women.

HIV-related health care

Comprehensive HIV/AIDS care and treatment is a central element of the Botswana National AIDS Policy. The programme is made up of voluntary testing and counselling, preventing, managing and treating opportunistic infections, and ART. Voluntary testing and counselling (VCT) is one of the main entry point for accessing other HIV/AIDS care and since 2000, the Botswana government, with CDC support, has established a network of Tebelopele centres providing immediate high quality, confidential services for sexually active Batswana aged 18–49. In January 2004 routine testing was introduced at all public health facilities to encourage citizens seeking health care to get tested.

Management of opportunistic infections is also provided free at health centres throughout the country. Tuberculosis (TB) is one of the leading causes of death among AIDS patients. HIV/AIDS has reversed the gains made by what was previously a very successful TB programme. In response, the Ministry of Health implemented a National TB Register and piloted an Isoniazid Preventive Therapy (IPT) programme that is currently being rolled out to the whole country.

In health facilities, fluconazole (Diflucan®, donated by Pfizer) and cotrimoxazole are available at no cost. However, the impact of these preventive therapy programmes is hampered by low uptake of HIV testing and weak referral linkages between VCT centres and health facilities. Furthermore, most individuals who present to hospitals are already at an advanced stage, and have therefore missed the benefits of preventive therapy. The introduction of ART has provided an impetus for testing and may serve as an entry point to promote and increase uptake of preventive therapy services.

Provision of antiretroviral therapy

In March 2001, President Mogae announced that the Botswana government would provide antiretroviral medicine free to all citizens of Botswana who need it. This programme became known as Masa (Setswana for 'dawn'). The ACHAP (The African Comprehensive HIV/AIDS Partnerships) provides financial and technical support (detailed in the next section).

An assessment of the Botswana health care system and infrastructure was carried out in May 2001, led by the National AIDS Coordinating Agency, Ministry of Health officials, ACHAP and consultants from McKinsey & Company (working on a pro bono basis). The team concluded that a national AIDS treatment programme could be realistically and practically implemented using a phased roll out approach to reach a total of 110,000 peo

[1] Abstain, Be faithful, use a Condom

ple in need of treatment over the next 6–8 years, by targeting selected patient groups in four key catchment areas. Strategic recommendations to implement the programme concerned the wide scale recruitment of skilled human resources, strengthening capacity for HIV diagnosis and testing, the implementation of counselling, education and support services, and a developed IT infrastructure.

The aim in the first year was to build capacity (human resources, infrastructure, equipment and systems) to serve 19,000 patients in four sites. It was unclear what the actual uptake would be when the programme began. High priority groups were identified in advance so that health providers would know which patients to prioritise in cases where excess demand required the tightening of eligibility criteria. Adult patients with CD4 counts under 200 and/or AIDS defining illnesses were prioritised along with those suffering from tuberculosis, mothers, and their babies and partners. Otherwise the programme was launched on a first come, first served basis. In January 2002, the first ARVs were dispensed in Gaborone at the Princess Marina Hospital and, by September 2002, 2,200 people had been enrolled and 1,500 were on triple therapy. A year later, in September 2003, 12,000 people had been enrolled and over 8,000 eligible patients were receiving treatment across six sites.

Despite these considerable successes, the Botswana experience also sheds light on the challenges of providing ART, beyond ensuring the availability and affordability of drugs, particularly the recruitment of sufficient trained staff, the maintenance of adequate infrastructure and health system support for service delivery.

Compared with elsewhere in sub-Saharan Africa, Botswana currently has tremendous capacity in terms of numbers of health workers, although they are currently severely under-utilised. Although achieving the full complement of staff to run the programme will require additional recruitment and infrastructure, there are more than enough staff to launch the programme and run it for some time. On the other hand, their lack of ART-specific training is a key limitation to scaling the programme up and the current model of care is top heavy and doctor-centred. A community-based model using supervised mid-level providers could increase capacity, and moves in this direction are under consideration.

The infrastructure for delivering ART is based in hospitals and clinics, which are run through two different ministries that have a complex relationship. Most hospitals continue to manage routine follow-ups although these could be referred to clinic level to reduce hospital workload and increase slots for new patients. However, this needs to be balanced with the current high levels of adherence and low risks of development of resistance. While the cost of drugs is less of an issue for Botswana than elsewhere in the region, upgrading hospitals and clinics to have adequate secure storage and drug management systems remains a major constraint.

In terms of health system support for ART services, the large number of fragmented and vertical initiatives introduced by various development partners, including the donation programmes (for example with varied training exercises) seriously reduces the numbers of functional staff actually available for individual programmes, even though in the aggregate staffing appears sufficient. Vertical programmes are partly the result of development partners' concerns with control over resources and implementation as well as programme monitoring. Nonetheless, currently monitoring and evaluation of ART delivery needs much more attention and is also a limiting factor in the roll out of the programme.

3. Drug access PPPs for HIV/AIDS programmes in Botswana

Policy context for access to HIV/AIDS drugs in Botswana

Botswana has registered and currently uses branded products for its selected ARV regimens, in public and private sectors. Most of the donated and discounted drugs are still under patent in their main markets, although the patent for Diflucan® (fluconazole) has recently expired, and generic versions are available. Neither Stocrin® nor Crixivan®, the two ARVs donated by Merck, are patented in Botswana. For others still under patent, such as nevirapine (NVP) and the fixed dose combination of zidovudine (ZDV) and lamiduvine (3TC), there are generic substitutes currently manufactured by companies based in India. These are not registered for use in Botswana.

The international policy and legal environment for improving access to treatment for HIV/AIDS is an extremely volatile one, which is unlikely to stabilise in the near future. There is great uncertainty about the role and future of branded products versus generic substitutes. Issues include market growth and competition; the impact of intellectual property rights legislation on affordable access to new products; reliability of supply and price reductions; quality assurance, product leakage and arbitrage; and development of resistance and treatment adherence.

This uncertainty is in part due to the implications for developing countries of bringing their intellectual property regimes into line with TRIPS, the WTO's framework for minimum standards on Trade Related Aspects of Intellectual Property Rights. While least-developed countries have until 2016 to develop TRIPS compliant legislation, middle-income developing countries such as Botswana must comply by 2005. TRIPS includes provision for public health flexibilities of compulsory licensing, and for parallel importation from countries where patent holder rights are exhausted.

The impact of strengthened patent legislation on the pharmaceutical market is difficult to predict. For example, the implications of India's compliance with TRIPS in 2005 on its pharmaceutical industry is still being assessed, in terms of how broadly patent rights will be applied. It is also unclear if the generic industry will respond to stronger intellectual property protection by expanding into new product and generics markets in OECD countries, as opposed to high volume, low cost deals for ARVs in developing countries.

Botswana currently registers and uses only branded ARVs. The government is closely observing the situation in South Africa, where patents have been issued for many ARVs. The Competition Commission has recently issued a ruling on the prices of branded products, which may influence prices. Of equal interest are the new out-licensing arrangements developed by R&D companies such as GSK, Merck Sharp & Dohme and Boehringer with companies in South Africa and India.

The development of more fixed dose combinations (FDC) to aid patient adherence and to further reduce costs, is also seen as an urgent priority. Indeed, in March 2004, Gaborone was the location for an international technical meeting hosted by the USA on FDC standards and quality assurance processes. Two Indian companies are already producing a fixed dose combination drug for triple therapy. Assessing the therapeutic effectiveness and bio-equivalence of these products is difficult because there are no equivalents registered by R&D companies with US or European drug regulatory agencies.

WHO has already developed a pre-qualification process to assess good manufacturing process in generic and branded manufacturers. Several R&D companies have also recently indicated that they are seeking to collaborate in the production of fixed dose combinations based on patented product combinations.

The financial and technical feasibility of delivering treatment interventions for HIV/AIDS in low and middle-income settings is still under review, and

approaches in most countries are in development. The evidence base for clinical and operational research for scaling up is lacking. For example, there is much debate on the individual effectiveness of the single dose maternal nevirapine for preventing infant infection, versus the risk of resistant strains developing in the mother and indeed in the wider community – thus compromising the effectiveness of a recommended first line therapy.

There is also growing international commitment to the need to provide treatment as a human rights, public health and economic imperative. The WHO 3 by 5 initiative reflects this commitment. A recent mission took place in Botswana in early 2004, and an operational plan was presented to NACA in mid 2004. Increased finance is available from the Global Fund to Fight AIDS, TB and Malaria, and the USA financed PEPFAR fund. Botswana has one Global Fund proposal that has been approved, but not disbursed, and PEPFAR funding, due to come on stream in 2004. While NACA is taking the lead in managing these inputs, there are concerns about coordination of finance, planning and implementation processes.

In some respects, Botswana has access to the infrastructure and resources that can enable it to make the most of current opportunities. There is strong political commitment from the President, who has declared the epidemic as a national emergency. It was one of the first countries in sub-Saharan Africa to begin providing treatment, by private clinicians in 1997, by Debswana in 2001 and public facilities in 2002. It now has significant experience on which to draw, and a relatively strong and well-financed public health sector within which to locate the treatment programme.

Developed through a major consultation process in 2002–2003, the National Strategic Framework 2003–2009 sets out priorities across sectors, together with budgetary estimates. The government has allocated sufficient additional resources from the development budget to the national HIV/AIDS response, which includes the ARV treatment programme. Major development and research partners are also committed to scaling up the ARV programme. The country is also facing several major challenges, in terms of human resource capacity, infrastructure, the need for rapid scaling up, and sustainability questions.

The programmes and partnerships

The partnerships in which Botswana is engaged represent a range of models, in terms of the types of inputs provided by the pharmaceutical company. These range from provision of the product alone, to programmes with additional technical inputs such as training and materials, and to much more complex 'development partnerships' such as demonstrated by ACHAP, where the product donation is just one of many components. These models are described below, and relevant features are summarised in Table 5 and Annex 3.

Viramune® Donation Programme (VDP)

HIV prevalence among pregnant women has increased from 34.5% in 2002 to 37.4% in 2003 (NACA 2003). With about 40,000 deliveries annually, up to 6,000 infants may be HIV-infected (assuming 40% transmission, in the absence of prevention).

Starting in 1999, Botswana was both the first country to initiate a programme for the prevention of mother-to-child transmission (PMTCT), supported by UNICEF, and also to roll out national coverage in the public sector, achieved by November 2001. The national PMTCT programme's goal, set out in Botswana's NSF 2003–2009, is to achieve a reduction in infants who are HIV-positive at 18 months to 10% in 2009, by providing treatment to all HIV-positive pregnant women. An early donation of AZT was provided by GSK (managed through UNICEF for the first 5,000 treatments for mothers).

Treatment is offered by all public health facilities providing antenatal care under the two line ministries, for facilities under Local Government and Health (over 600 in total), and by private/not for profit facilities supported by the government.

The PMTCT programme now uses a two-drug regimen. Single dose nevirapine was added to the AZT (at 34 weeks) regimen in 2003. The VDP provides free short course nevirapine to all women qualifying for PMTCT treatment from 2003 to 2007, through the public health system and government supported facilities. The donation programme is almost entirely product- based, unaccompanied by other inputs.

With the limited evidence base available, debate continues within the PMTCT and ARV advisory committees about the risks of community and individual resistance to nevirapine versus regimen

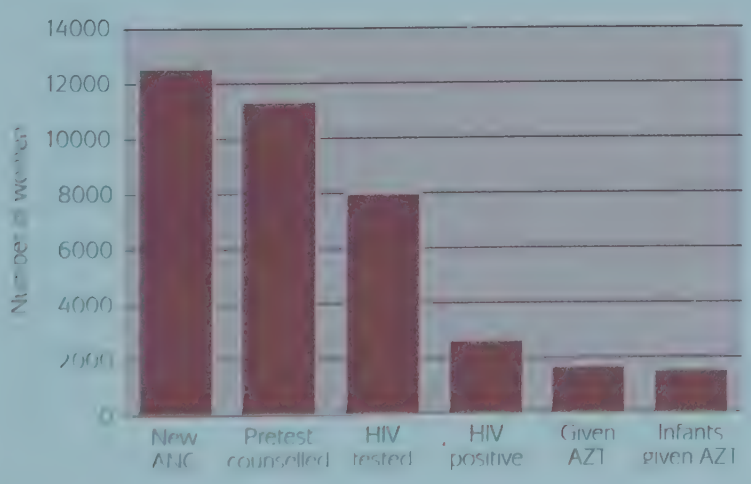
effectiveness. There were some reports that a few facilities are not providing nevirapine, despite national guidelines, except to women seeking maternal health services late in their pregnancies. This has been recently addressed by the MOH.

In addition to the VDP and UNICEF, other international partners include the Botswana Harvard Partnership (with Harvard AIDS Institute), undertaking research into PMTCT treatment strategies, and the Baylor Children's Centre, providing support to paediatric care. Botswana is also one of 14 eligible countries for the White House Initiative for PMTCT. The BOTUSA Project (Botswana Ministry of Health, the U.S. Center for Disease Control and the Global AIDS Programme) is managing a US$ 3million grant in 2003–2004 to strengthen PMTCT, with focus on community capacity development.

Current levels of programme take-up (measured through take-up of AZT treatment at 34 weeks by all pregnant HIV-positive women) were felt to be low at 36% in 2003, but are increasing slowly. Barriers include women's reluctance to be tested and their felt need for their partner's permission, failure and delay in returning for test results, stigma and low community awareness. Rapid tests and the new routine testing policy introduced in January 2004 are likely to help increase take-up. The acceptability of formula feeding is felt to be increasing in some areas, but low in others. The effectiveness of this intervention to reduce risk of transmission during breastfeeding may also be reduced by the reported use of mixed methods, both formula and breastfeeding.

Challenges include developing better integration with the ARV programme at both central and facility levels. Pregnant women who qualify for treatment (thought to be about one-quarter of ANC clients) need to be referred appropriately. Ideally, the baby's HIV status could be monitored using diagnostic facilities provided by the ARV sites. There is some evidence from facilities that cross-referral is already successfully taking place. The PMTCT programme also seeks to provide stronger support and follow-up to women after birth (in use of breastmilk substitutes, counseling, support groups, etc.) and community education and mobilization to increase uptake.

National PMTCT programme uptake Q3 2003



Source: PMTCT Newsletter, FHD/MOH

Diflucan® Partnership Programme (DPP)

Fungal infections, including cryptococcal meningitis (CM) and oesophageal candidiasis (OC), are common opportunistic infections (OIs) in Botswana, after TB. Their management is included in the national OI guidelines, as part of comprehensive HIV/AIDS care, first developed in late 1990s. Botswana continues to purchase very limited quantities of Diflucan® by special order for severe fungal infections non-indicated under the DPP.

Since the DPP's beginning in mid-2002, the drug has been provided through public sector distribution channels to all 32 government and government-supported hospital facilities, in all districts. There are no programme performance targets, and drugs are provided on a needs basis. As of February 2004, nearly 290,000 tablets had been distributed, although data on coverage is not easily available. Pfizer has also supported patient management and treatment uptake through provision of 'train the trainer' courses (with IAPAC, International Association of Physicians in AIDS Care South Africa), training materials, and patient information.

Discount arrangements with Accelerating Access Initiative companies

The AAI was established at international level in May 2000 to help increase access to HIV/AIDS care and treatment in developing countries, including high burden middle-income nations. It is now a partnership of the UN with seven research-based companies. (Abbott Laboratories, Boehringer-Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, F. Hoffmann La-Roche, Gilead Sciences and Merck & Co., Inc.). AAI provides a framework for bilateral company-government negotiations, and does not necessarily involve UNAIDS or other UN organizations.

MOH and the supplying companies in Botswana have individual 'gentlemen's agreements' (no signed agreements or MOU in place) with the companies participating in the AAI except Merck (handled via ACHAP). The GoB set up a cross-government Task Force for ARV Drugs Price Negotiations in 2001, in view of its intention to launch an ARV treatment programme in 2001–2002. The Task Force met with individual company representatives to agree initial supply arrangements and prices, according to the AAI framework. Thereafter, companies have continued to offer price reductions to Botswana, in line with overall company discount strategies.

The government-negotiated prices are for distribution in public sector or government supported clinics. Significant (but lower) discounts are also negotiated by wholesalers serving the private market, particularly for use by the insured sector.

Drug donation by Merck (component of ACHAP)

Stocrin® and Crixivan® are offered as donations to Botswana by Merck for use as antiretroviral (ARV) drugs in the treatment of HIV/AIDS. The national ART programme is one of the government's major and widely known HIV/AIDS interventions. As one of the drugs for first line treatment, the provision of Stocrin® is therefore making a significant in-kind contribution to the national anti-retroviral therapy (ART) programme. The donation is one aspect of a broader commitment by the Merck Gates Foundation partnership to addressing the HIV/AIDS epidemic in Botswana, through the ACHAP partnership.

Some of ACHAP's most widely recognized contributions are its efforts in supporting the government in starting up the programme, also known as the *Masa* (meaning 'dawn' in Setswana) programme. Botswana is the first African country to provide free ART to all its citizens. The programme was initiated in January 2002 when there was considerable global and domestic scepticism about the viability of ART in sub-Saharan Africa. However, with prevalence of HIV/AIDS amongst the adult population reaching 36.8% in 2001, and growing evidence for its social and economic impact, the provision of ART became imperative for the government. It was also hoped that through provision of ART, it would be possible to increase awareness and education about HIV/AIDS and that this might contribute to reduced levels of transmission of the disease.

Beyond the request for the donation of Stocrin® and Crixivan®, the government also asked ACHAP to perform a series of tasks to support the start-up of the ART programme. First, ACHAP procured the services of McKinsey & Company, a management consulting group with experience in the health sector, to conduct a feasibility study for an ART program in Botswana. McKinsey provided these services pro bono and ACHAP absorbed travel and per diem costs for McKinsey consultants for a period of eight weeks. Further to this feasibility study, ACHAP also recruited and seconded to government an ART programme manager. This manager was one of the McKinsey consultants who had conducted the feasibility study.

Beyond the need to understand the feasibility of ART and to set up the management of the programme, the government faced other constraints, primarily related to limited physical infrastructure and inadequate numbers of skilled health care workers. ACHAP was keen to support the development of capacity to deliver an effective and high quality ARV programme, including for drug and patient management systems.

The MOH's ARV programme proposal requested ACHAP to build 20 clinics for ART treatment and to provide additional secure storage space for ARV drugs at the Central Medical Stores (CMS). ACHAP's cumulative financial commitment to physical infrastructure development for the ART project was US$ 2.7 million by December 2003.

ACHAP also agreed to recruit and to pay for 54 of the 247 additional health care workers required for the first phase roll out of the ARV programme. ACHAP agreed to pay these workers for a period of two years, beyond which the government would continue to employ and pay these workers. Thirty-three of these posts have now been filled.

In an attempt to improve the skills of health care workers, ACHAP provided financial resources to the healthcare worker training programme jointly implemented by the Government and the Harvard AIDS Institute (the Botswana Harvard Partnership), the Knowledge and Training Shall Overcome (KITSO) programme. Overall ACHAP commitment to KITSO in December 2003 was US$ 2.8 million.

Table 5. Features of HIV/AIDS related drug access PPPs in Botswana

PPP	Discounted ARV arrangements (AAI participating companies)	Viramune® Donation Programme	Diflucan® Partnership Programme	Stocrin® and Crixivan® donation through ACHAP development partnership
Programme objective	Make available ARVs to according to AAI 2000 framework principles	To provide Viramune® free for preventing mother-to-child transmission of HIV infection in the public sector	To make Diflucan® available free of charge for HIV-positive patients with OC and CM in the public sector	To provide Stocrin® and Crixivan® as a component of ACHAP, in addition to technical and financial contributions to support the effective use of ARVs
Programme initiation	2001, negotiations with five companies involved in AAI (GSK, BMS, Roche, Abbott, Boehringer)	2003, following decision to include nevirapine in PMTCT regimen (Boehringer proposed partnership in 2001, when Botswana initiated PMTCT)	July 2002, following offer by Pfizer in 2001	2002, at request of Government, following decision on national treatment protocol. Stocrin® is part of first line regimen. Crixivan® is not part of any regimen, but small amounts are used.
Eligibility and timescale	Indefinite. Provided to eligible patients accessing ART in Government and government-supported facilities.	Five years to 2007. Maternal health service users accessing all government and government-supported facilities.	Indefinite. Eligible patients accessing 32 government and government-supported facilities.	Included in 2000–2005 ACHAP agreement. Provided to eligible patients accessing ART in Government and government-supported facilities.
National partners	MOH (and CMS), NACA. Several research partnerships also access lower prices.	MOH (and CMS), NACA, Ministry for Local Gov. Also UNICEF, Baylor Children's Centre, BOTUSA in wider PMTCT programme.	MOH (CMS), NACA	MOH, MOF, NACA, Ministry for Local Gov. ACHAP, plus wide range of public and private partners in ACHAP.
Budget contribution	ARVs currently financed by Government; about 2/3 ART programme costs, and will double by 2009 (NSF).	None identified – donation procured and provided through existing system.	None identified – donation procured and provided through existing system.	None identified – in kind donation, complementing GoB and ACHAP inputs to ARV programme.
National coverage	Supplied in line with public sector ARV programme coverage to public facilities (14,400 patients, about two-thirds female, April 2004) and government-supported facilities in corporate private sector.	National public sector programme providing PMTCT services in hospitals and clinics (under local Government ministry) providing ANC and/or delivery services. 36% of pregnant HIV-positive women accessed programme in 2003 (40,000 ANC pop, with approx 15,000 HIV-positive).	Provided nationally through all 32 government and government supported MOH health facilities, including primary hospitals. No data on coverage and impact. About 290,000 tablets distributed between April 2002 and Feb 2004.	Stocrin® supplied in line with public sector ARV programme coverage– prescribed to about 55% of patients.
Drug supply and reporting system	Procured by CMS from companies (often SA based). Treated as high security Schedule 1 drugs, requisitioned and distributed through national drug supply management system.	The PMTCT programme liaises with Axios International procurement services, using CMS data. Donation is distributed through national supply system. Treated as Schedule 1 drug with separate dispensing register and ordering of donated product for PMTCT (as opposed to product purchased for ARV treatment).	CMS uses Axios International procurement services. Drug treated as Schedule 1, with separate drug registers (provided by the DPP) detailing individual named patients by facility and collated by CMS on a monthly basis.	CMS forecasts needs based on monthly facility reports, for processing and managing by ACHAP with Merck. MSD South Africa supplies drugs to CMS, for distribution and reporting using Schedule 1 procedures through national system.

Table 5. Continued

PPP	Discounted ARV arrangements (AAI participating companies)	Viramune® Donation Programme	Diflucan® Partnership Programme	Stocrin® and Crixivan® donation through ACHAP development partnership
Conditionalities	Public sector and government supported programmes.	Public sector and government supported programmes. Reasonable reporting requirements.	Public sector and government supported programmes. Reporting requirements felt to be burdensome but useful – could be better adapted to Botswana's system.	Public sector and government supported programmes. Reasonable Standard Operating Procedure agreed by Merck and GOB,
Performance against targets	Uptake considered low against Year 1 target of 19,000, but increasing as more facilities develop capacity.	36% uptake considered low, given 100% target for 2009.	No targets, uptake based on demand.	Uptake considered low, but increasing as more facilities develop capacity.
Sustainability	High level commitment to ARV programme. Botswana is considering various options for medium and longer term to reduce programme costs, including generic drugs procurement.	High level commitment to PMTCT programme Boehringer agreement would be reviewed if Botswana changes treatment policy to e.g. short course HAART regimen including NVP.	Should the donation cease, government would consider options, including registering and purchasing of generics through competitive procurement.	Uncertainty and limited discussion so far about extending donation in line with ACHAP extension to 2007. Unclear whether budget forecasts include the very significant value of the donation.

Additionally, ACHAP finances and manages an on-site training programme for healthcare workers, the preceptorship programme. Preceptors educate and provide practical training in AIDS care and prevention for health workers in Botswana. Preceptors are recruited through ACHAP partnerships with the University of Pennsylvania, the Academic Medical Centre at the University of Amsterdam, and St Stephen's AIDS Trust (including Chelsea and Westminster Hospitals). Over 1,300 healthcare workers had been trained by preceptors in December 2003.

ACHAP has also supported various measures to support the uptake of ART and adherence to ART. ACHAP recruited an information, education and communication (IEC) consultant to start up and manage the IEC programme. To ensure sustainability, government assigned a local counterpart to the consultant, who would develop and eventually manage the programme. ACHAP was also responsible for starting up an IT-based patient management system, through provision of hardware, selecting and buying software, as well as recruiting IT staff to manage the system at facility level.

Key findings

Country priorities and policies

Without exception, the donation and discount programmes are supporting access to products required for the delivery of HIV/AIDS-related health services to all Batswana in need of treatment, who are using the public health system. These priorities are set out in the National Strategic Framework for HIV/AIDS 2003–2009.

The drugs provided are fully in line with government standard treatment protocols and national guidelines. As summarised in Annex 4, the programmes also comply with WHO guidelines for drug donations and discounted single source offers. Companies have had no direct involvement in drug selection for national regimens. For example, company representatives are not included in national advisory or treatment guideline committees (in part to prevent risk of anti-competitive behaviour).

Merck offered to donate Stocrin® and Crixivan® in 2000, when ACHAP was initiated. Anticipating the possible start-up of an ARV programme, Merck preferred ACHAP funds be used to support a range

of HIV/AIDS interventions, rather than toward purchasing drugs that Merck could donate. Merck did not participate in the high-level government meetings to decide on the start-up of an ART programme. However, government officials interviewed for this study largely agreed that the presence of ACHAP and the availability of a free first line ARV helped to give them the confidence to move forward to establish the programme. Government currently chooses to use its own resources, as opposed to ACHAP funds, for other ARV drug procurement.

The ARV clinical advisory committee decided to select only one drug offered by Merck through ACHAP (efavirenz/Stocrin®). Stocrin® is used as a part of first-line therapy for all adult males, children over five years and females who are not at risk of having children or cannot tolerate nevirapine. However, due to regional demand, negotiations to receive the 50mg tablets required for paediatric use had just been finalised in May 2004. Indinavir/Crixivan® was excluded as first, second or third line therapy in the 2002 treatment guidelines as its administration is complex in resource-limited settings. However, small quantities have been ordered by CMS.

For the PMTCT programme, the decision to add single dose nevirapine to the AZT-only regimen was not taken until 2003. Nevirapine was included for technical, evidence-based reasons, and well after Boehringer initiated discussions with the government to begin the Viramune® Donation Programme in 2001.

However, there is major debate in Botswana concerning the longer-term risk to public health of including a single dose of nevirapine in the regimen. This could contribute to the development of resistant strains that would jeopardise the effectiveness of Botswana's first line regimens. Botswana is faced with several policy choices, which may have implications for the VDP, including using short course dual or triple therapy.

Fluconazole treatment was included in national treatment guidelines for opportunistic infections and available (in limited quantities to hospitals on special order request) prior to the initiation of the Diflucan® Partnership Programme. Diagnostic requirements pre and post the donation programme are the same. Special orders were also limited to CM and OC, before the introduction of the programme. The Botswana treatment guidelines (as well as most guidelines including WHO's) recommend amphotericin B for the acute phase of CM, which is purchased by the CMS out of the MOH's essential drugs budget. Donated fluconazole is used only for the lifelong maintenance phase.

The DPP agreed to donate the intravenous and paediatric suspension formulations for fluconazole. However, at the time of the study, these had not yet been provided, although the donor was reported to be making arrangements to provide the latter.

Concerning broader issues, some interviewees felt that the patient information materials supplied by Pfizer under the MOU with the government are not compatible with GoB's generic drug policy. These materials provide valuable information on recognizing and treating the two indicated conditions. However, the leaflet includes the banner of the Diflucan® Partnership Programme, and the Pfizer logo, and does not mention fluconazole, the generic name. Not using the generic name in patient information is contrary to the government's National Drug Policy, and could have longer term implications. Should the donation cease or the government make alternative plans for procuring the drug, this could compromise prospects for generic substitution, in terms of patient adherence. This is an issue especially for CM, as lifelong maintenance is required using fluconazole to prevent relapse.

Several interviewees at central and facility level mentioned that this could be seen as 'clear advertising of a brand to clinicians and the general public', whilst others felt it was less of an issue, given that the leaflets are in English and little used by patients. The DPP Working Group is currently translating and adapting the leaflets into Setswana. In contrast, the DPP wall charts and training materials use both brand and generic names. The vast majority of prescribers and dispensers use the generic name in accordance with government policy.

Merck does not provide extensive training materials or engage in advertising its donation of drugs. At the district level, few doctors prescribing Stocrin® were aware that it was a donated drug. Some other AAI companies have also offered to provide continuing medical education and patient materials for HIV/AIDS and other conditions, as part of their broader support to improving access to effective treatment and care in developing countries. It is not clear whether the MoH has or will take up these offers.

Ownership and governance issues

There is no strong central coordinating function for the drug access partnerships. Agreements are variously held by the MOH (but managed by different units in liaison with CMS), NACA and the Ministry of Finance. This means that the policy position on drug access partnerships is not strongly developed, in terms of a consistent approach to price and timeline negotiations or conditionalities. With respect to the donations, there was some feeling that: 'if you get something for free, don't stir the water'. Whilst it is clear that the government determines how donations should be managed, this could lead to a less equally negotiated partnership than desirable.

This also applies to procurement of discount products. For example, negotiations with companies participating in AAI took place in 2001, and the government has been benefiting from further price cuts as offered by the companies (for example GSK's end-2003 offer). However, some informants felt that Botswana could adopt a more robust negotiating position, in view of its ARV rollout plans. Others felt that patient volume would be too low to warrant additional discounts. As yet, government is only beginning to systematically review comparative price information available from WHO and other sources, which could strengthen its negotiating position. Government also has minimal information on any deeper price reductions achieved by other countries, which companies tend not to make available.

There were mixed views regarding the impact of indefinite versus fixed time periods for the drug access programmes. An indefinite timeframe presents challenges to forward budgeting processes. On other hand, fixed terms carry risk of donor withdrawal, but enable better planning, monitoring, benchmarking, and dealing with inefficiencies. There appears to be no agreed policy position yet on whether the Stocrin® donation will be included in ACHAP's agreement to extend disbursement of committed funds until 2007.

Governance and accountability arrangements do not involve direct and close involvement of companies within government structures. The exception is the Diflucan® Programme Partnership Working Group, established by the MOU between the MOH and Pfizer to oversee the donation programme, which includes a Pfizer representative. While this is felt to be a reasonable arrangement, the MOH is clear that partner companies should receive similar treatment as other development partners, with respect to public relations, for example. The Group meets quarterly and oversees professional training and education, supply logistics and reporting quality. Pfizer is also entitled to carry out independent drug management audits. One such has taken place, which reported no accountability problems.

One of the key features of ACHAP is that it works primarily to support government led initiatives. ACHAP does not implement parallel or independent programmes to address HIV/AIDS, but works according to priorities set out in the NSF, under NACA's co-ordination. All proposals for ACHAP funding are developed with NACA and relevant line ministries, with some ACHAP involvement, and have to be approved by the relevant ministry at national level and then by the Applications Review Committee (ARC) which is chaired by the Permanent Secretary of the Ministry of Finance and Development Planning. Final approval is by the ACHAP Board, which includes Merck, Gates and Harvard AIDS Institute representation.

Programmes that ACHAP has contributed to, such as the ART programme, are widely seen as government-owned. However, the ACHAP logo is used at district level, on buildings built or refurbished using ACHAP funds, and publicity describes ACHAP as 'handing over' clinics to the MOH.

Strong government ownership and leadership in the ACHAP partnership is reflected in the management of the donation of Stocrin® and Crixivan®. Merck donates these drugs through the CMS and is not involved in the process of storage or distribution of drugs. Supply of the drugs is, reasonably, contingent on ACHAP receipt of forecasts from CMS, which can lead to delays. CMS, in liaison with the ARV programme, is responsible for providing ACHAP with forecasts for drugs required (using software provided by ACHAP) and ACHAP forwards these requests to Merck. ACHAP has not dedicated any personnel to managing this drug donation and it is one of the many responsibilities of ACHAP's financial operations manager.

Integration with general health services

The donation partnerships are well embedded within their wider operational programmes, in terms of their management and implementation.

As discussed above, ACHAP's initiatives have been primarily motivated by government objectives and requests, and are largely integrated into government-led interventions.

Costs to the public sector: Indirect costs of the drug access partnerships are not felt to be excessive, and are certainly less than the transaction costs of alternative procurement arrangements. Indeed, several interviewees mentioned their acceptance of a reasonable 'a price to pay' for donations (in terms of reporting and accounting responsibilities) and the need 'to keep their side of the bargain'. Costs are mainly in DPP reporting at facility and central level. In total, DPP, VDP and Stocrin® reporting and forecasting take about three days a month at central level. None of the donation programmes have dedicated full-time personnel at CMS. CMS has appointed one full time ARV officer to ensure that the tight security systems are maintained. CMS personnel have expressed that if DPP were to provide an easy-to-use software for the monitoring and compilation of the information, it would make reporting much simpler and easier.

Links with other programmes: The extent of integration and coordination between the various AIDS related programmes, and within the wider health system varies greatly. However, this is in line with most health system development trends in sub-Saharan Africa, where ARV programming and financing may promote a new generation of vertical programmes. Indeed, the Botswana ARV programme is making substantial efforts to develop cross-programme links, through a facility level model to support integrated ARV service delivery.

One in three adult Batswana are HIV-positive, but due to low testing uptake, the vast majority are unaware of their HIV status. Many adults presenting to health facilities have HIV-related conditions. However, until the availability of treatment, there were few incentives to obtaining an HIV test. With the availability of ART, HIV/AIDS is no longer perceived as a death sentence but as a chronic disease by those who test positive. The ART programme is therefore widely seen to have facilitated the establishment of routine testing for HIV/AIDS in all public health facilities, starting January 2004. Potential patients testing positive are now referred to the ART programme for evaluation and possible treatment.

Links with disease-specific vertical health programmes such as TB, STIs and PMTCT are perceived as rather weak, especially at central level and in referral facilities where a 'dedicated' ARV team is running the ARV clinic. However, in some district hospitals, staff report good collaboration with other programmes, and TB patients and pregnant women with possible AIDS symptoms are now normally referred for treatment registration. This trend is supported by the development of the 'integrated' team model – where all facility clinicians are trained in ARV treatment management and work within the clinic on a rotation basis.

HMIS and public health surveillance: There is a perceived necessity to speed up the collection and processing of data required to inform the HIV/AIDS policy response and programme management. Data collection activities of the ART programme and NACA's planned HIV/AIDS information system may generate some duplication in public health surveillance and health management information functions, with the statistics unit for example. Whilst these are important challenges for integration of new and existing systems, they are not directly linked to requirements of the drug access programmes.

The ARV programme, with ACHAP funds, has developed an urgently needed user-friendly IT system for facilities delivering treatment, to support patient and drug monitoring. While it is as yet unclear how and whether the new Integrated Patient Management System will use this system, it is clear that IT and human resources inputs (data technicians) are contributing to computer literacy in the health service. It has also created interest in, and demand for, a new and needed cadre to deliver the IT function required across the health service.

Drug management systems: CMS is responsible for the management and distribution of all discounted ARV drugs; donated ARV drugs (Stocrin®/efavirenz) and Viramune®/nevirapine, and donated Diflucan®/fluconazole. PMTCT compile and submit monthly drug utilisation reports for Viramune® to Axios International, using data provided by CMS. However, supplies are distributed to health and district clinics by CMS, as part of the drug management system. The drug donation aspect of ACHAP is fully integrated into general health services in that it does not require extra or strikingly different forms of reporting on drug use. Nor does it insist on any unusual forms of justification for the prescription of Stocrin®. However, ACHAP has provided software that is used for monitoring the drug distribution.

Indeed, some facility level informants were not aware that either Stocrin® or Viramune® for PMTCT were donated. This is possibly linked to the fact that facility pharmacies are not responsible for financial management of their drug budget, and therefore tend to have little awareness of the price to government of any of the drugs prescribed or dispensed.

All ARVs (and Diflucan®) are treated operationally as Schedule 1 drugs (traditionally reserved for habit-forming drugs), and are subject to high security provisions. These products are stored at CMS, MOH and local government facilities under lock and key, and transported in lockable vans. These are received immediately they reach the site (CMS or facilities) and are checked and stored at once. Facilities have a system in place for accounting for drugs received and drugs issued to patients. There is a computerized system for some of the sites but this is complemented by manual record keeping. For ARV drugs, facilities use a register similar to that used for recording controlled drugs while for donated fluconazole, facilities use a similar register supplied by the donor.

Drug security has been improved at CMS and MOH facility level, with some ACHAP investment as described above. Several of the partnerships provide differentially packaged drugs (GSK's Combivir®, Pfizer's Diflucan® tablets for public sector, versus capsules for private sector). This is seen as a useful supportive measure.

There may be opportunities for pilferage lower down the system. Drug management and security is thought a little weak by some interviewees at primary hospital and clinic level – while basic measures are taken (for example locked cabinets), overall security awareness is sometimes limited.

However, there are few reports of leakages. Overall the drug market is perceived as reasonably controlled. It is an offence to import non-registered drugs. Customs officials, the police and the Drug Regulatory Unit are seen to be quick-acting and effective. The few reported instances of internal and external leakage, and the consequences for those involved were recounted by several informants at all levels and in public and private sectors. However, with scaling up of free access, and the growth in both legal and illicit ARV markets in neighbouring countries, the risk of arbitrage in and out of Botswana will grow.

While the reporting system for all ARVs and the DPP is more stringent than existing practice, it is felt at central level that the wider system should be aspiring to these kinds of standards, in terms of patient and drug monitoring. These procedures are also demonstrating to health workers the value of patient management information over time. The CMS and Essential Drugs Action Programme are working to strengthen reporting systems at facility level. However, while serving a useful purpose in demonstrating a possible model for improved drug and patient management, the DPP reporting system is perceived as a little burdensome in terms of time, and could be better adapted to the national system. When implemented, plans for further computerization at CMS and facility level will ease the pressure.

Health and health system impact

There are very limited data on overall health impact. For ARV and OI treatment, this would include data on long-term treatment outcomes, quality of life and productivity. It is somewhat early days for this type of information. As yet, the PMTCT programme also lacks information on the numbers of children who have/have not seroconverted by 18 months, which would be a measure of its overall impact. Lack of impact data is recognized as a serious issue, and is being addressed.

However, there is good data on ARV programme coverage, including numbers of patients treated, and mortality and adherence rates. PMTCT also provides quarterly data on various take-up indicators (see VDP section). CMS provides details on reported incidence of CM and OC and units distributed per facility, which indicates demand by providers at district level.

Impact of the donated and discounted ARVs is contingent upon the impact of the ART programme, through which patients access these drugs. The ART programme is in the process of rolling out and eventually Botswana hopes to have 32 sites across the country providing ART. Presently, 12 of these sites have been established. In several parts of the country, significant numbers of patients are still awaiting reasonable access to ART.

Even where ART is available, it is not always immediately accessible. As of early 2004, nearly 25,000 patients have been enrolled in the national ART programme. However, only 14,400 patients in the public sector have been initiated on ART,

Table 6. ART Programme enrolment and treatment

Site	Launch date	Tested with CD4<200/ AIDS defining/ children	Patients on ARV	Deaths on ARV	% deaths on ARV
Gaborone	Jan-02	11,366	5,834	550	9%
Francistown	May-02	5,032	3,640	283	7%
Serowe	May-02	3,024	1,784	169	9%
Maun	Jul-02	1,565	998	157	14%
Jwaneng	Apr-03	1,000	548	40	7%
Orapa	May-03	595	322	19	6%
Tutume	Oct-03	404	217	25	10%
Molepolole	Oct-03	414	155	11	7%
Mahalapye	Oct-03	762	669	34	5%
Kanye	Oct-03	441	233	10	4%
Total public		**24,603**	**14,400**	**1298**	**8%**
Private sector (insured and Debswana)			6,289	NA	NA
Grand total			**20,689**		

Source: Botswana National ARV Team Statistics, MOH, April 2004.
(NA = not available)

who are eligible for treatment. Human resource constraints and the burden of treating patients who are generally presenting themselves at advanced stages of the disease have been cited as reasons for the relatively slow provision of treatment to those enrolled. However, the rate of uptake is now increasing, as new sites come onstream. Capacity remains under pressure, with some facilities reporting temporary halts to enrolment.

Approximately 55% of patients on ART are on Stocrin®, as part of first line treatment. Some interviewees noted that the availability of these donated drugs allows the government to allocate its own resources towards many other pressing national needs. However, the precise impact of the donation remains unclear.

As described above, ACHAP is enabling investment in several human resource development initiatives for HIV/AIDS treatment. The preferred 'integrated model' is probably more sustainable in the longer term, but takes longer to develop. Train the trainer courses were provided to the MOH by Pfizer through Axios. The MOH continues to provide training to the health care providers on the diagnosis and management of CM and OC and also on drug management issues. Given the extent to which integrated ARV and opportunistic infections training is provided, there is some perception that additional training linked to the DPP is duplicative in light of combined ARV and OI training available through MOH and ACHAP supported KITSO programmes. On the other hand, several clinicians reported under-diagnosis of oesophageal candidiasis and felt that training was useful. KITSO does not cover the management of OI extensively, and some interviewees viewed training by DPP Task Force as beneficial in terms of increasing knowledge about OC and CM.

Impact of the availability of ART on the overall health system remains unclear, in terms of impact on resource allocation and human resources for example. However, the programme planning process has taken additional staff demand and impact into account. The initial assessment study in 2001 noted that, to meet the initial targets, the public health system would need to expand by 30% for doctors, 8% for nurses, 130% for pharmacists, and 62% for pharmacy technicians. However, in the short term, about two-thirds of these needs could be met through filling vacancies already budgeted for by government. Other posts have been supported by ACHAP, which provided 'bridging' finance in order for government to budget in the longer term.

Interviewees noted that the availability of ART reduces the burden imposed by HIV/AIDS on general health facilities by reducing numbers of opportunistic infections and hospitalisations. On the other hand, some facilities reported increases in patient numbers, with no corresponding increase in staff. In others, for example where a new ARV treatment clinic was set up, additional physical infrastructure and health care workers allocated to the ART programme allowed for general health staff to focus on other health concerns.

In the case of many of the earliest ART sites, this also brings challenges for integration. Here, the ART programme remains separate from general health services and functions as a special unit catering solely to patients requiring ART. Doctors involved in ART may not be involved with patients seeking care for possibly AIDS-related conditions, which can generate a time-consuming referral process for both staff and patients. Some recently developed ART sites were found to be more closely integrated with general health services and here, interviewees expressed considerable satisfaction with the extent to which the ART programme had alleviated the general health burden of the hospital. Making the transition towards greater integration with general health services remains a challenge for the early sites.

Equity issues

The government's policy is to make health services effectively free of charge to all Batswana. The public sector HIV/AIDS programmes support the free provision of treatment and care, including drugs. Of patients on treatment, about two-thirds are women. With regard to socio-economic aspects of equitable access, direct financial costs should not be a deterrent to anyone seeking treatment. However, indirect and opportunity costs can be great, in terms of travel time and costs, time off work for treatment, and may have a serious impact on take-up and adherence (monthly prescription refills, monitoring visits etc).

Data on the socio-economic status of patients, and the degree to which the programmes are enabling (or not) the equitable distribution of resources is lacking. However, the team heard several anecdotal reports about the problems for some of the poorer people in accessing and continuing treatment. Effort is certainly made to address these problems. For example, food baskets are provided through district social welfare services to those on treatment assessed as in need. Some clinics permit stable patients to pick up prescriptions every three months. Transport expenses are reported to be provided in some districts.

Financing, scale and sustainability

Concerns about sustainability beyond ACHAP are related to government's capacity to attract and remunerate appropriate human resource capacity and to absorb the costs of the donated drugs. The ART programme faces several constraints in the process of rolling out to 32 sites. Key amongst these constraints is the lack of human resources. This is seen to be particularly problematic in sites where the ART programme remains un-integrated with general health services and requires a dedicated team of health care workers. New sites are likely to be more integrated into general health services.

To meet human resource requirements for a fully rolled out programme, the government is considering proposals for including private sector doctors and pharmacists in the delivery of national ART (see Challenges). It is also considering the pros and cons of redefining the roles of some health cadres, for example to allow nurse practitioners to prescribe ARV refills and pharmacy technicians to dispense ARVs, without a supervising on site pharmacist. This would enable follow-up and monitoring of stable patients to be delegated to staff at clinic level, but may be a risk to the high adherence rates.

The value of the drug donations in monetary terms appears to be played down by their sources and by the government. It is striking that few interviewees were inclined to put a monetary value on donated products, although the assumed savings to the system were much welcomed. In the case of the Stocrin® donation, this could amount to well over US$10 million per annum (at current discounted prices of US$ 500 per person per year, prescribed to about half of all patients), if 50,000 people are on treatment by 2005. The cumulative value will obviously be far greater over the full programme period.

The donation of Stocrin® and Crixivan® is set to continue until the end of 2005, when ACHAP was originally intended to end. With the extension of ACHAP to 2007, the government has requested that Merck consider extending the period for the drug donation, but at the time of the study this had not been formally agreed. However, although it is clearly committed to financing the ART pro-

gramme, there is little evidence that the government has developed specific plans to absorb the costs that will be imposed upon its finances once this donation is discontinued. As mentioned earlier, the government has not systematically accounted for the value of the donation within its budget. This has implications in terms of sustainability planning.

The ART programme is financed mainly by government (excluding value of drugs donated). ACHAP's overall financial commitment towards the implementation of the ART programme by December 2003 was approaching US$ 6 million, with a further commitment of about US$ 10 million. Whilst critical to ARV programme start up, this amounts to under 20% of total ACHAP funding, and only about 10% of the total ARV programme budget.

Some 23% of the HIV/AIDS budget in Botswana in 2003 was spent on the ART programme, with drugs amounting to about 50% of costs (not including the value of donated products). This is the largest category of expenditure within the HIV/AIDS budget. The initial assessment for the ART programme estimated that, in order to reach the five-year target of 110,000 patients on therapy, US$ 680 million would be required over the period, rising from an initial US$ 28 million for the first year.

Estimated total treatment costs per patient of US$ 1,500 (as per estimates in the initial assessment) are set to rise as patients develop resistance to first line regimens and require more expensive second line drugs. While up-to-date analysis of the costs and benefits of ARV treatment is lacking, this figure represents a very significant six-fold increase in the current national per capita government health spend of about US$ 125. Currently, drugs and diagnostics are estimated to cost about US$ 800-1000 per person year.

According to recent WHO estimates, the average price for a quality assured first line regimen is US$ 484 (ranging from US$ 85 to US$ 555). Botswana pays approximately US$ 720 for the first line treatment with nevirapine, and US$ 230 for the non-donated components of the other first line regimen, which includes donated efavirenz. Hence, for as long as the donation continues, the total cost for both, about US$ 950, is roughly equivalent to the average price quoted by WHO. However, if the Merck donation ceases, the cost will rise to over US$ 1,400.

There are further concerns about the significant investments required to sustain treatment, as opposed to prevention, in the context of Botswana's commitment to an 'AIDS free generation'. This is highlighted in the NSF, where figures are broken down to show the costs allocated to the goal for provision of care and support, and the difference with and without the ARV programme (over 50% versus 38% of costs).

In response, the government is allocating substantial additional resources. Botswana's AIDS response is funded through the development budget allocated to the Office of the President for coordination and disbursement by NACA. The total allocation in 2004–2005 is 11% of the budget, at about US$ 100 million, and almost double the initial estimate made a year previously.

Perceived benefits

Interviewees valued the PPPs greatly, and found the companies to be flexible partners. Some positive impact is widely reported, and reflected in the data, in terms of increased access to drugs (coverage and take-up rates of ARV, OI and PMTCT treatment), although it is acknowledged that take-up rates of both ARV and PMTCT treatments are lower than targeted.

Beyond ACHAP's financial contributions, access to international consultancy and health networks have been useful for staffing the ART programme. Once the Government of Botswana has made a decision to take forward a proposal, and it has been approved by ACHAP, access to ACHAP's financial and technical resources can enable programme start up and implementation in a much shorter time period than would be possible under normal procedures. Over the period of the partnership, this complex role has developed and is now variously described as: catalyst; bridge builder; jump starter; facilitator; and gap filler. Its results-based approach, and streamlined operating procedures have made it a useful mechanism through which government is able to implement initiatives quickly. ACHAP is acknowledged to be performing a facilitative role with government in supporting wide debate and consultation on sensitive issues such as the introduction of routine testing in January 2004.

In the medium term, the government is strongly committed to taking over the responsibility for these functions, and hence sustainability is built in. This is a challenging model for both government

and ACHAP partners, and has been criticized as being non-competitive (for example by bypassing some procurement procedures for infrastructure development). On the other hand, it has enabled the relatively swift development of systems, and the deployment of resources, for responding to a national emergency that has been prioritized by the President.

Outstanding challenges and opportunities

Private sector providers and drug access

Scaling up access to treatment to meet the 2005 target of 50,000 will require significant expansion in capacity. Botswana has a few hundred private practitioners, most of whom are organized and working within a reasonably well-regulated environment, with many registered with the medical aid insurance schemes. There were some reports that some private sector patients have been prescribed non-recommended regimens, especially before national guidelines were developed. As patients become less able to pay, they were sometimes prescribed dual instead of triple therapy. However, it is also evident that government has not yet provided significant support to private sector training initiatives, although individuals can self-pay for training courses offered by the MOH and KITSO training programmes.

Botswana's three insurance schemes cover about 160,000 public and private sector employees, and already provide about 4,200 patients with ARV treatment. They have developed a managed care approach to clinical and financial management, and involve a network of preferred providers and wholesalers. The main insurance agencies have adopted a managed care approach to clinical and financial management of patient care, and provide an advisory service based on the national ARV treatment guidelines for all the practitioners registered with them.

At present, the insurance agencies have no access to government-negotiated donations and discounts, although they do benchmark against government prices and negotiate in line with them, achieving quite sharp discounts. The insurance industry has also agreed limits with wholesalers and retailers on mark-ups on ARV drugs (capped at 15%), as opposed to about 50% for other products. In terms of achieving maximum value for public money, there is a strong argument that those covered under public sector insurance schemes should also benefit from the reduced prices available to government.

Drug sourcing and intellectual property rights legislation

Botswana is one of the few sub-Saharan African countries currently using branded products only for HIV/AIDS related treatment, in both public and private sectors. Only branded ARV drugs are currently registered with its Drug Regulatory Unit, although several applications from generic companies are awaiting review.

Botswana has recently set up a Patent Office and begun to accept patent applications, as it prepares to comply with WTO's TRIPS framework legislation by end 2005. It is working closely with ARIPO, the African Regional Industrial Property Organization based in Harare, which aims to coordinate and support TRIPS compliance and review processes for patent application for its members. Currently no pharmaceutical companies hold patents in Botswana, although over half the applications submitted to ARIPO members are reported to concern medical products.

Botswana's Ministry of Trade is finalizing several amendments for the Industrial Properties Act 1996, in order to make it TRIPS compliant. With regard to the TRIPS permitted public health flexibilities, the legislation already includes compulsory licensing. Officials are considering an amendment to enable provision for parallel importing. However, whilst there was high awareness about public health needs, there was some anxiety about the response of pharmaceutical companies. Some in the MOH also felt that the response to necessary changes in legislation had been slow. The need for increased and formal cross-governmental working on trade, public health and intellectual property issues was mentioned.

Policy development in a rapidly changing environment

Clarity on future donation policy and intentions is important, although certainly very challenging in the rapidly changing treatment environment. For example, in the context of current debate about appropriate PMTCT regimens, Boehringer-Ingelheim's Viramune® Donation Programme is exploring treatment strategies in the context of current debate about the effectiveness and risks of the various PMTCT regimens.

Boehringer "recognizes that in addition to programmes involving single dose Viramune® given alone to mother and child, there are other regimens where short courses of other ARVs are provided to the mother prior to birth and to the newborn child. BI accepts these modalities and does supply Viramune® to such programmes. The essential aspect however is that the programmes and the supporting infrastructure are adequately in place to ensure the welfare of the mother and her infant. BI will continue to supply free of charge single dose Viramune® used alone or in combination within the VDP for PMTCT, as there is a special need in developing countries where chronic treatment is not yet readily available. BI will continue to support research into new solutions to improve prevention of MTCT." (personal communication, July 2004).

Clearly, use of a short course triple or dual therapy during pregnancy that included nevirapine (as opposed to a single dose regimen) has financial implications. Current estimates in South Africa run at US$ 180 per treatment.

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4. Conclusions and recommendations

Impact and equity issues

The donation partnerships and discount arrangements are fully in line with government priorities and policies. The PPPs also strongly comply with WHO guidelines for drug donations and discounted single source offers.

Some positive results are reflected in the data, in terms of increased access to drugs coverage and take-up rates of ARV, OI and PMTCT treatment, although take-up rates are felt to be lower than desired, and there is no data on impact. However, the limiting factors are not linked with the access programmes, but with wider system capacity issues. What is less clear is the extent to which the distribution of programme benefits, including the drugs, is equitable or reflects Botswana's income distribution. The assumption that the free public sector programmes serve mainly low income groups may hold true in urban areas. This is less likely in rural areas where indirect and opportunity costs are significant. Programme rollout will address equity issues to some extent.

While this issue is not directly linked with the drug access programmes, it does raise serious questions for health services in general about the overall strategy for resource allocation, including drugs, and the need to develop ways to ensure inclusion of the poorest and marginalized, and for measuring and disaggregating data on treatment access. A monitoring system that includes assessment of socio-economic status is recommended to support the design of appropriate strategies for tackling any inequities.

PPPs and private providers

Scaling up access to ARVs using the public sector only will present significant challenges to the programme. National level PPPs with private sector clinicians and pharmacists would provide a mechanism for managing and monitoring the delivery of care to publicly funded patients. Proposals outlining a national PPP approach involving publicly funded managed care networks of private providers are being discussed in national fora. A feasibility study was undertaken by an MOH in 2003 and proposals have also been put forward by WHO's 3 by 5 mission that explored overall scale up issues for the ART programme.

There are some concerns in government about scaling up this approach, including challenges of patient follow up and monitoring, drug security, loss of public sector doctors and pharmacists, and the nature of private sector (made up of lone practitioners, often expatriates). However, it also presents an opportunity for very significant expansion of service provision and could be extended to other essential health services.

An outstanding policy question is the willingness of pharmaceutical companies to extend donation and discount offers to the private sector, as a contribution to scaling up treatment strategies. Such a scheme would use public sector finance to pay providers through a managed care or franchise scheme, with appropriate patient and drug monitoring. There are initial signs that some companies may be willing to extend offers to such a scheme. The proposals under discussion in Botswana represent a significant opportunity for an innovative model that brings together national and international PPPs to improve access to medicines.

Partnership models

Since the first agreement with the government in 2000, companies are developing their involvement – to greater and lesser extent – as new and valued development partners in Botswana. A range of models involving industry partners is in place, from products only to products plus provision of technical and financial support. The complex and rapidly changing policy and technical environment is presenting challenges and opportunities. Innovative and flexible approaches are required. While a

company's desire for measures to ensure effective use and accountability is justification for reasonable reporting conditionalities, a range of models is clearly needed, according to context and health system capacity.

An important feature of the implementation of the drug access partnerships in Botswana is the use of the national drug supply and management system. This demonstrates company commitment to tailor their accountability requirements to country context and capacity. For example, for the provision of Diflucan® and Viramune®, very few, if any, additional inputs are needed to ensure effective use and accountability in a system with demonstrable existing capacity, such as that in Botswana.

ACHAP provides an example of a system-strengthening model. ACHAP is seen to be a particularly effective PPP because it works primarily to meet government's requests and does not support parallel systems duplicating government efforts.

Coordination, planning and sustainability

The perception that: 'if you get something for free, then don't stir the water' is a concerning one. Although government is clearly managing the donation programmes for the benefit of its citizens, it is recommended that drug donation or discount arrangements are approached as a contract with both partners actively negotiating and agreeing terms. Such an approach would certainly be in line with the government's existing good practice in tendering and contracting procedures.

The lack of a strong central overview of drug access partnerships may mean that opportunities are missed in terms of developing a consistent approach to price and timeline negotiations or conditionalities. Short-term gains need to weigh against the longer-term risks of donation agreements, by both government and company partners. Long-term plans regarding sustainability and drug choice if the donation were to cease in the future need to be considered when entering into an agreement. A broad framework for PPP operation could facilitate a balance between predictability and consistency, with sufficient adaptability and flexibility to meet the needs of specific programmes.

It is important for both partners to agree clear and consistent messages about the nature of the partnerships, the value of donated inputs, and sustainability questions. It is striking that very few interviewees were inclined to put a value on donated products, which for the Stocrin® donation is very significant. Whilst clearly valued as a saving to the system, all in kind contributions appeared to be excluded in financial terms for the purposes for budgetary planning. This has serious implications for sustainability planning.

Drug quality, pricing and promotion issues

Botswana uses only branded products for HIV/AIDS treatment at present. Merck supports government officials in their view that current drug selection policy is for the 'right drugs at the right price', irrespective of brand versus generic status. The government has concerns about generic quality and reliability of supply. In addition, there are some perceptions that may limit Botswana's range of choices in the medium and longer term. First, in the context of intellectual property rights, some expressed caution about industry's response to the introduction of public health flexibilities into domestic intellectual property legislation. Second, there is also perceived understanding among some interviewees that the discount agreements with R&D companies might mean that the MoH is restricted to use of their branded products only. In this context, it should be noted that currently there are no pharmaceutical patents registered in Botswana.

Shared understanding is needed between industry, government and other partners on these potentially sensitive issues. These perceptions may have longer-term implications in terms of value for money questions. Discount agreements can contribute to a downward pressure on prices (in markets where competitor products are also available). However, while donation programmes are greatly valued by recipients, their long-term indirect effects can rule out local competition, particularly if the recipient perceives any obligation to use a sole source. The situation with fluconazole provides an interesting case in point. The patent has expired, but no applications for generic registration have been made. Therefore, while the public sector benefits from Diflucan® donations, fluconazole cannot be procured in cheaper generic form by the private sector, including by insurance providers who are purchasing drugs and treatment services for public sector employees.

Sourcing less expensive generics is not seen as a priority, as for now the government can afford the branded products and has confidence in their quality standards. For as long as the Merck donation

continues, the total cost of the two first line regimens per year is roughly equivalent to the average price quoted by WHO. Scale up has also been lower and slower than expected, hence expenditure on drugs lower than budgeted. With a free public sector service, and a small private market, there is also limited public pressure to reduce cost to consumers.

For the medium and longer term, quality assured fixed dose combination generics could contribute to greater coverage and adherence, particularly in the context of ARV scale up plans and sustainability. Officials are ensuring that all options are open to government, in terms of maximizing their leverage in competitive procurement and/or bilateral negotiations for better prices. The Ministry of Trade leads on developing appropriate intellectual property legislation, which is intended to include public health flexibilities in line with the WTO's TRIPS Agreement. The MOH is monitoring international moves to improve quality and good manufacturing practice, including the WHO's prequalification service, the AIDS Medicines and Diagnostics Service, is starting to examine the generic market, and is following policy developments for fixed dose combinations.

In the context of discount and donation agreements, ongoing monitoring is also needed for approaches to continuing medical education, product promotion and public relations, sometimes offered or provided by the company. For example, aspects of the DPP's patient information materials contravene widely accepted generic drug policy principles on patient information, by omitting the generic name of the drug. Should the donation cease and/or the government make alternative plans for procuring the drug, any brand preference developed among consumers or prescribers could compromise prospects for generic substitution.

Annexes

Annex 1. Study Terms of Reference

Annex 2. Persons interviewed

Annex 3. PPP Programme information

Annex 4. Compliance with interagency guidelines for drug donations and discounts at country level

Annex 5. Bibilography

ANNEX 1

Study Terms of Reference

Impacts of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries

Summary

The Initiative on Public-Private Partnerships for Health, in association with the Institute for Health Sector Development, proposes an extension (Phase II) of its previous work, the purpose of which would be to:

- Conduct a further three country studies of drug donation or discounted pricing programmes in low-income countries, in particular to evaluate their operations, and health and health system impacts. Countries proposed for such studies are Botswana, Sri Lanka and Zambia, on each of which a detailed report will be prepared;
- Prepare a synthesis of findings, conclusions and recommendations across all countries and programmes, including those studied in the Uganda Pilot Study; and
- Disseminate these reports to a range of relevant audiences.

Background

The health consequences of poverty lead to major health inequities for poorer populations in developing countries. Many health problems among populations disadvantaged by poverty have been neglected because of lack of commercial incentives or have proven intractable when tackled by public sector or NGOs independently.

In recent years, a number of collaborations have arisen to tackle specific problems. These are usually targeted to specific products, diseases or technologies.

One particular group of these public-private partnerships (PPPs) addresses access to pharmaceuticals (usually drugs) that are critical to treatment or care for tropical diseases which disproportionately or uniquely affect the poor in developing countries. This category of partnerships for drug access is usually based around the provision of products that are donated, heavily discounted or in some way subsidized by their producer (usually a 'sole source'). They entail a multi-partner effort at field level to ensure the distribution and proper use of the medications. These access partnerships are in many instances the only initiatives likely to be mounted for some diseases, especially those that do not rise high on the political visibility scale (e.g. lymphatic filariasis, trachoma and sleeping sickness compared with HIV/AIDS, tuberculosis, and malaria). They are accepted by the governments of countries to which they are offered, and by the populations reached, for the health benefits they provide.

Other types of public-private partnership have been established to encourage pharmaceutical companies to reduce the prices of (and sometimes donate for free) drugs which treat diseases which exist in both rich and poor countries – for example, HIV/AIDS and malaria. Here, the multi-partner initiative generally focuses on negotiating different (or tiered) prices across markets – with the most preferential prices reserved for public sector services in developing countries which are assumed to be accessed by the poorest. These types of initiative have generated more controversy due to the difficulties of establishing what are considered to be 'fair' prices in different markets and the problem of arbitrage – or leakage between those markets. Furthermore, they are more difficult than the drug donation programmes above to classify as 'PPPs', since they are not necessarily distinct from normal government purchaser-pharmaceutical provider contracting processes (such as NHS bulk purchasing arrangements) and are heavily influenced by the presence (or not) of generic equivalent products in the market.

Both types of public-private partnership raise a number of questions, mostly relating to their integration with, and impact upon, the broader development of health services in countries in which they operate. The key question is the degree to which

the involvement of multinational R&D pharmaceutical companies in some stage of drug procurement and delivery facilitates better drug availability and access by the poor. Further questions include whether the availability of free/reduced price drugs distorts decisions on priorities or prices and what the feasibility is of taking such initiatives to scale, and their sustainability. This range of questions becomes of greater importance as the number of targeted partnerships in particular countries increases and as countries have to prioritise their use of resources within the context of debt relief, Sector-Wide Approaches (SWAps) in health, and multisectoral Poverty Reduction Strategic Plans (PRSPs). Issues of integration, coordination, implementation and impact need to be addressed at all levels within countries – national, regional, district and community.

The UK Department for International Development (DFID) is funding the Initiative on Public-Private Partnerships for Health (IPPPH), part of the Global Forum for Health Research, to conduct a series of studies across a range of access partnerships and countries.

Phase I: Pilot study in Uganda, 2003 (completed)

A pilot study to assess the health and health systems impact of public-private partnerships for improving access to pharmaceuticals in a selected low-income country was undertaken in Uganda in May 2003. It covered tropical disease programmes for leprosy, lymphatic filariasis, onchocerciasis and sleeping sickness, and three HIV/AIDS PPPs: the UNAIDS Drug Access Initiative/Accelerated Access Initiative, the Viramune® Donation Programme and the Diflucan® Partnership Programme. The study also pilot tested a study protocol and research instruments for further studies. A full report on the pilot study is available.

Phase II: Three more country studies, a synthesis paper and dissemination

DFID is now funding IPPPH to:

- **Undertake three further country studies** including at least two studies of HIV/AIDS PPPs and two of selected tropical disease PPPs. The countries – Botswana, Sri Lanka and Zambia – have been selected to ensure that, together with the Uganda study, the maximum number of global drug access partnerships is examined, including major active tropical disease partnerships. The study in Sri Lanka will specifically examine whether the country is benefiting from all PPPs for which it is eligible, or should be eligible by comparison with other countries participating in the PPPs.
- **Examine supranational level issues** including how the specific drug donation or discount price programmes operate at global level, how they relate to broader partnerships in which they participate, and how they relate to the countries examined.
- **Prepare a synthesis paper** of all the work and conclusions, including the pilot study. The purpose of the synthesis paper is to compare and contrast for policy makers the potential implications, cost, benefits, and risks of drug donations and discounted pricing schemes for contributing to expansion of access to appropriate treatment or control of diseases that primarily afflict poor populations. The synthesis shall also note for policy makers, pharmaceutical companies, and other actors (such as NGOs or funders) operational options that can maximize health and health system benefits and reduce any potential undesirable impacts of such arrangements.
- **Develop and implement a dissemination strategy**, which will communicate the key findings, conclusions and recommendations of the studies to a range of relevant audiences including national policy makers, bilateral and multilateral aid funders, pharmaceutical companies and non-governmental agencies.

Objectives

The specific objective of the current studies is to assess the health and health systems impact in the selected countries of public-private partnerships for improving access to pharmaceuticals in relation to HIV/AIDS and to tropical diseases, where pharmaceutical companies are involved as partners at some stage of programme design and/or implementation. The key research question concerns the degree to which the involvement of multinational research and development-based pharmaceutical companies, as partners in supplying free or discounted drugs, facilitates drug availability and access by the poor.

The studies should map the key features of the PPPs, and examine the relationship between the specific drug donation or discount price pro-

grammes, the broader partnerships in which they participate and the countries examined.

At country level, the studies will examine issues of ownership, regulation, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of these access PPPs as distinct from other comparable programmes where drugs are competitively procured (for example, the World Bank's MAP, the GFATM or generic purchasing activities). They will review the PPPs in relationship to country health systems and the broader context, both vertically (e.g. how the PPPs relate to pharmaceutical policies, donor/funding issues, broader partnerships) and horizontally (e.g. perceptions and impacts of the partnership from both PPP and government perspectives).

Key issues for examination should include:

- The respective roles of PPP programme partners, governments and local interests in the partnership at global and country level, including developing programme proposals, decision-making, conditionalities and governance, their motives and interests in being involved, and levels of support/funding.
- The extent of the PPP programme's integration with national disease programmes and broader health planning.
- The programme's involvement in, and the effectiveness of, any coordinating mechanisms (formal and informal) with other PPPs at all levels, and any consequences of the PPP programme studied for other PPPs (e.g. in terms of creating opportunities or barriers for other PPPs).
- Evidence available on the impact on (a) coverage and (b) health, including the impact of any inclusion in the PPP programme design of efforts specifically to reach poorer populations, women and children, and measurement of coverage by socio-economic status, rural/urban mix, gender and age.
- The impact of the PPP programme on health systems, including the outcome to-date of any specific PPP programme objective to strengthen health systems. This would include perceptions of impact on: use of staff time; staff skills; drug ordering and delivery systems; planning and monitoring systems and MIS/HMIS; government-NGO working relationships.
- For ARVs, the effects of different models of drug supply on regulation, drug procurement and drug distribution. In addition, their impact on equity of access and product availability/prices in both public and private sectors.
- Views on the optimal scale of the programme's operations within the country, and any plans for taking the programme to scale and for longer-term sustainability.
- Identification of the specific benefits and challenges, if any, arising from the involvement of pharmaceutical companies in disease-specific PPPs.

Outputs

The outputs for the country level work in this second phase of activity will be individual reports on the three further country studies.

Methods

Rapid assessments: These are rapid assessments rather than detailed studies. Documentary, quantitative evidence should be obtained wherever available. However, it is recognized that these are likely to be largely qualitative studies making extensive use of semi-structured interviews with key informants. Given funding and time limitations, the studies will not undertake significant original data gathering.

Country studies: The precise range of programmes will vary from country to country.

Fieldwork in each country will be undertaken in a two-week visit by a team of international and national consultants. Undertaking the work in a two-week visit will require effective pre-visit preparation and the prior development of base documentation on the country context and the individual PPP/programmes.

The country studies should adopt a layered approach to evaluation, covering the country context and the disease control policy before assessing the individual partnership programmes. Fieldwork will include interviews about each programme at national, regional (where appropriate), district and health facility levels. Criteria for selection of districts should include:

- Active implementation of those PPP programmes being studied, ensuring that each programme is visited in at least one district. HIV/

AIDS programmes should be examined in the capital and at least one contrasting district.

- Regional and socio-economic representation.
- Security and accessibility, within the timescale of the study.

Fieldwork should include interviews about each relevant programme at national, regional (where appropriate), district and health facility/community levels.

ANNEX 2

Persons interviewed

Government of Botswana

Central level

Ministry of Health

Dr Moeti, Deputy Permanent Secretary
Mr John Botsang, Chief Pharmacist
Dr Ernest Darkoh, Operations Manager, MASA ARV Programme
Mr S Ramotlhwa, Principal Pharmacist 1, MASA ARV Programme
Dr Seipone, Coordinator, AIDS/STD Unit
Dr Jimbo, AIDS/STD Unit
Mr D. Mapiki, Principal Pharmacist, Central Medical Stores
Ms M. Moipolai, Central Medical Stores
Dr Joyce Kgatlwane, Essential Drugs Action Programme (also MOH nominated study counterpart)
Dr Selelo, Drugs Regulatory Unit (DRU)
Ms Mpho Mogodi, PMTCT Programme

National AIDS Co-ordinating Agency

Dr Banu Khan, National Co-ordinator

Ministry of Finance and Development Planning (Economic Affairs)

Mr Mompati Nwako, Director Budget Administration
Ms Grace Muzila
Mr Cornelius DeKop
Mr Joseph Willie
Mr Benjamin Baakile

Ministry of Local Government

Dr Obita, Head, AIDS Co-ordinating Unit

Ministry of Trade and Industry

Mr Mophuting, Head Industrial Property Section

Development partners and others

ACHAP

Mrs Tsetsele Fantan, Project Leader,
Mr Brad Ryder, Communications
Ms Colleen Blumton, Operations Manager

ACHAP Board

Dr Linda M. Distlerath, Vice President, Global Health Policy, Merck & Co., Inc.
Mr Samir A. Khalil, Executive Director, HIV Policy and External Affairs, Merck & Co., Inc.

Botswana Harvard Partnership

Dr Ibou Thior, Project Director
Dr Onalethata Johnson, Researcher
Mr Richard Leepo, Researcher

UN partners

Dr Ampomah, UNAIDS Country Coordinator
Dr Veskov, Epidemiologist, WHO (3 by 5 mission consultant)
Dr Eyob Tseqaye, Medical Officer, WHO
Ms Connie Osborne, PMTCT, UNICEF

Botswana Network of People with AIDS (BONEPWA)

Mr David Ngele, Coordinator

Private Sector

Mr Duncan Thela, Managed Care Advisor, Associated Fund Administrators Botswana (Pty) Ltd
Mr Johan Moolman, General Manager, Medswana (Pty) Ltd (wholesalers)
Dr Gordana Cavric, Consultant Physicina, Gaborone Medical Center and member of Society of HIV Clinicians, Botswana

District and facility level

Princess Marina Hospital, Gaborone

Dr Ndwapi Ndwapi, Director IDCC (ARV clinic)

Mahalapye Government Hospital

Dr Bose, Hospital Superintendent
Mr Robert Ogenyi, Hospital Pharmacy
Dr Sikombe, IDCC (ARV clinic)

Debswana Jwaneng Mine Hospital

Dr Thato Moumakwa, IDCC ARV Coordinator
Ms Mogana, Matron

Ms Msipha, Sister, ANC service
Ms Lindiwe Mokone, Hospital Pharmacist

Kanye Seventh Day Adventist Hospital
Dr Mwantembe, Chief Medical Officer and IDCC
Mr Robert Zvavamve, Pharmacist
Ms Melody Morei, Social Worker
Ms Cally Mabusa, Midwife and ANC

Nyangabwe Hospital, Francistown
Mr Anthony Ozane, Principal Pharmacist

Gantsi Primary Hospital
Dr AS Mrindoka, Medical Officer
Dr Hirui Mehreteab, Chief Medical Officer
Mrs Lebotse, PMTCT Focal Person
Ms Margaret Ntuane, Pharmacy
Mr B Gaosengwe, Pharmacy
Ms B Lenong, Senior Nursing Sister, Gantsi Village Clinic
Mr Gilbert Mumba, Midwife, GVC

Maun Government Hospital
Dr FAP Claessen, Preceptor Doctor
Dr Mudiayi, Physician Specialist and IDCC
Mr Jude Nwokike, Principal Pharmacist

ANNEX 3

PPP Programme information

Viramune® Donation Programme (VDP)

Assessment of disease in national/district health strategy and plan

VDP is a component of the national PMTCT programme, which is key to achieving goal 1, impact indicator 1.3 in the HIV/AIDS National Strategic Framework 2003–2009. The MOH developed a national plan for the PMTCT programme in 2000, setting out the strategy for national coverage. This is currently being redrafted to drive better integration with the ARV therapy programme, and to take into account changing policy with respect to treatment in light of concerns about nevirapine resistance.

HIV prevalence among pregnant women has increased from 34.5% in 2002 to 37.4% in 2003 (NACA 2003). With approximately 40,000 deliveries annually, about 15,000 babies are at risk of HIV infection through MTCT, with up to 6,000 HIV infected (assuming 40% transmission, in the absence of prevention).

PMTCT programme goal (NSF 2003)

To achieve reduction in infants, born to HIV-infected mothers, who are HIV-positive at 18 months, from a baseline of 40% in 2002, to 20% in 2006, and 10% in 2009.

To increase the percentage of HIV-positive pregnant women receiving a complete course of prophylaxis, from 34.3% in 2002, to 70% in 2006, and 100% in 2009.

VDP goal, objectives and strategy

To provide free short course nevirapine to all women in need for five years from 2003–2007, through the public health system and government supported facilities.

Nature of partnership

Partnership between MOH and Boehringer-Ingelheim, set to run for five years (2003–2007). UNICEF provides technical and research assistance to the PMTCT programme. PMTCT programme liaises with Axios International for Viramune® supply, using data provided by the CMS. MOH is initiating discussion with Abbott for donation of DETERMINE rapid test kits.

Programme start date, stage of development and future plans

The VDP started in 2003, following an initial application in 2001. VDP was not started until the MOH decision was made to add single dose nevirapine to the AZT short course provided to women during pregnancy, in light of the accumulating body of evidence showing increased reduction in transmission with the use of two drugs.

The PMTCT programme started in 1999, with technical assistance from UNICEF, and a donation of AZT from GSK (managed through UNICEF to cover the first 5,000 doses). Botswana was the first pilot country working with UNICEF, and the first to roll out national coverage, achieved by November 2001.

Future plans include developing better integration with ARV programme at both central and facility levels, so that pregnant women who qualify for treatment can be treated appropriately (approximately 25%) and for monitoring the baby's HIV status using laboratory facilities provided by the ARV sites. There is some evidence from facilities that cross-referral is already taking place. The programme also seeks to provide stronger support and follow-up to women after birth (in use of formula, counselling, support groups, etc) and community education and mobilisation.

Possible changes to the regimen are still being discussed by relevant advisory committees, in light of the risk of developing nevirapine resistance.

Governance arrangements and location of manager

The VDP is managed by the PMTCT programme in the MOH's Family Health Division. BI has no involvement with governance or management decisions, and provides no additional material for training or patient education. The PMTCT Programme is under the PMTCT Technical Advisory Committee, which includes UNICEF, BOTUSA, Botswana Harvard Partnership and others, and a larger PMTCT Reference Group (NAC, senior government officials). Also falls within remit of the ARV Clinical Advisory Group.

Mode of operations

PMTCT is offered by all public health facilities providing ANC under both line ministries, Local Government and Health (over 630 facilities), and private/not for profit facilities supported by the government. PMTCT compile and submit monthly drug utilisation reports to Axios International, using data provided by CMS. Supplies are delivered to CMS, and distributed to health and district clinics, as part of the drug distribution system. Donated Viramune® is stored separately from ARV supplies, and a separate drug register is kept by antenatal clinic staff.

Current geographical and epidemiological coverage and impact

The treatment is offered to all women accessing ANC and delivery services (reported at 100% by MOH, but anecdotal evidence suggests lower coverage in some districts where poverty and distance limits access). Local government clinics with maternity units stock and prescribe both NVP and AZT for PMTCT. It is not clear that all ANC clinics are keeping or using NVP for women presenting late in pregnancy.

Overall take-up is felt to be low – about 36% of all pregnant HIV-positive women initiated treatment in 2003, which was a significant improvement on 2002's 28%. There is no data on sero-conversion of children by 18 months – existing data shows low numbers of positive children, but could be due to high mortality of HIV-positive babies. Barriers include women's reluctance to be tested and their felt need for their partner's permission, not returning for test results, and low community awareness. Rapid tests will reduce drop out, as will the new routine testing policy introduced in Jan 2004. Effectiveness of intervention reduced by use mixed feeding (formula and breastfeeding) by some of the mothers.

Links with other programmes

Botswana Health Partnership (with Harvard AIDS Institute) is undertaking research into PMTCT strategies, and also receives donated Viramune®. Baylor Children's Centre supports research activities and the National Paediatric IDCC at Princess Marina Hospital. Botswana one of 14 eligible countries for the White House Initiative for PMTCT. BOTUSA is co-ordinating a grant of US$ 3million in 2003-2004 to strengthen the programme, with focus on community capacity development. The MOH has initiated negotiation for donated test kits with Abbott Laboratories.

Issues

Value added

The VDP is contributing to the national PMTCT programme's coverage of all women accessing antenatal and delivery services. Conditionalities appear minimal and reasonable.

Comments

There is uncertainty regarding the treatment regimen of choice, given ARV scaling up plans and the unclear evidence base upon which to agree drug protocol. There is ongoing debate between the three technical committees concerning the addition of single dose nevirapine in 2003, and risks to ARV programme effectiveness in future. Some facilities were not providing nevirapine to women receiving the AZT short course, in spite of national protocol, although this has now been addressed by the MOH. However, the debate does not appear to be influenced by the VDP.

At the time of the study BI indicated that it was exploring treatment strategies to avoid the occurrence of resistance after a single dose Viramune® regimen, and continuing to support research into new solutions to improve prevention of MTCT. Boehringer "recognizes that in addition to programmes involving single dose Viramune® given alone to mother and child there are other regimens where short courses of other ARVs are provided to the mother prior to birth and to the newborn child. BI will continue to supply free of charge single dose Viramune® used alone or in

combination within the VDP for PMTCT, as there is a special need in developing countries where chronic treatment is not yet readily available. BI accepts these modalities and does supply Viramune® to such programmes. The essential aspect however is that the programmes and the supporting infrastructure are adequately in place to ensure the welfare of the mother and her infant." (personal communication, July 2004).

Diflucan® Partnership Programme (DPP)

Assessment of disease in national/district health strategy and plan

Fungal infections, including cryptococcal meningitis and oral/oesophageal candidiasis, are common opportunistic infections (OI) in Botswana.

Management is included in the national OI guidelines, as part of comprehensive HIV/AIDS care, which were developed in late 90s before the DPP was initiated. The third edition of these guidelines is currently being integrated with ARV treatment guidelines. Objective 2.3, under Goal 2 in the National Strategic Framework, is to increase the number of skilled health workers (doctors and nurses) providing accurate diagnosis and treatment of opportunistic infections, from a baseline of 590 in 2002, to 1,180 in 2006 and to 2,360 in 2006.

Prior to the introduction of the DPP in 2002, Diflucan® was available on a named patient basis, as a special order drug. The national treatment protocol is adapted from WHO preferred regimen, with amphotericin B indicated for CM acute phase. Fluconazole indicated for maintenance phase.

DPP goal, objectives and strategy

There is no programme strategy document, as the DPP is integrated into health services and OI treatment. The DPP's goal and objective is to improve access to effective treatment for cryptococcal meningitis and oesophageal candidiasis in patients with HIV. Since DPP's beginning in mid-2002, it has been provided through public sector distribution channels to all 32 government and government supported hospital facilities, in all districts. There are no programme performance targets, and drugs are provided on a needs basis. Pfizer has also supported patient management and treatment uptake through provision of train the trainer courses (with IAPAC), training materials, and patient information.

Conditionalities

Diflucan® should be prescribed only for the two specified indications. It must be distributed through state-funded institutions, including those with designated district status (32 facilities, including referral hospitals, district and primary hospitals, mission hospitals, two private sector mining hospitals and defence facilities). The MOU signed with Pfizer and the MOH includes a commitment on the government side to justify need for the drug (in terms of disease incidence) and account for distribution and use of the drug. Conditionalities therefore include Pfizer's standard requisition and reporting mechanisms for the programme (number of cases/patients and units prescribed on a monthly basis). The drug is operationally treated as a restricted schedule drug (as per habit forming drugs), and is therefore subject to tight security measures (kept under lock and key, double signature procedures). The information management system includes: new patient registration, re-admissions; details of referrals to clinics; consumption and number of cases; adherence to limitations on indications; drug utilisation reviews; expired stock; stock diversion; through monthly, quarterly and annual reports. The donated product is differentially-branded with a different colour and formulation (pill for public sector versus capsules for private sector).

Other inputs

Pfizer also provides patient information leaflets and initial 'train the trainer' support to professional training in Botswana under contract with IAPAC (International Association of Physicians in AIDS Care), South Africa. Leaflets developed for the South African programme in English have been provided by the DPP. These are distributed to facilities with the drug. MOH is currently adapting and translating these into Setswana.

Programme start date

Pfizer approached MOH in 2001, following the success of the programme in South Africa. The then Minister of Health was supportive of the DPP's introduction. Botswana MOH has had an MOU with Pfizer to supply Diflucan® since July 2002. National treatment protocol in place.

Governance and nature of partnership

The contract is between the MOH and Pfizer through the MOU. The Diflucan® Programme Partnership Working Group oversees the donation programme, which includes: Deputy Permanent Secretary, MOH; the Head of the CMS; staff from the Essential Drugs Action Programme and the AIDS/STD Unit; the ARV programme pharmacist; and representatives of pharmacists, paediatricians and clinicians from several health facilities. The Group also includes a Pfizer representative. It meets quarterly and oversees training, education, logistics, and reporting quality. Pfizer also entitled to send in auditors. One audit has taken place, which reported no accountability problems.

Mode of operations

The DPP is integrated into the national system for procurement, distribution, storage and dispensing of drugs. The drug is managed as per the high security system for habit forming drugs. The systems used for the record keeping are viewed as time consuming but do demonstrate accountability. The donor has provided each facility with a record book that provides information on quantities received and issued, remaining balance and also the type of indication prescribed for. CMS collates information provided by facilities and prepares a report for Axios International, contracted by Pfizer to supply DPP products. Both CMS report and order are approved by MOH Chief Pharmacist. The reports are submitted every six months or when the need to request for more supply arises. On average, CMS prepares the report every quarter.

CMS spends time collating the data form facilities and preparing the report. Their recommendation was that the donor should consider providing software that will make the handling of data easier and also for the donor to assist in the preparation of the report. There are no reports of leakage of Diflucan®.

Training is provided under management of the AIDS/STI unit in the MOH, with support of IAPAC. However, this is still being rolled out, and about 16 of 24 districts have received training. There is some perception that additional training linked to the DPP is duplicative in light of ARV and OI training available through the MOH and KITSO programmes. Others felt that specific training is needed due to low diagnosis of OC.

Budget

No financial limits, to be supplied for 'indefinite' period.

The regimen for acute phase CM is amphotericin B (as per Botswana treatment guidelines) and therefore incurs MOH expenditure. Donated Diflucan® is used only for lifelong maintenance treatment.

Impact, current geographical and epidemiological coverage

Supplied to all publicly supported health facilities. Nearly 290,000 tablets have been distributed between April 2002 and February 2004. There is no data on impact. CMS uses a pull ordering system and demand from hospitals varies – possibly the full need is not being met due to under-diagnosis.

Dedicated personnel

No dedicated full time personnel. Under overall management of Deputy PS/Deputy DG MOH. Costs to public sector mainly in reporting at facility and central level – approx two days a month at central level.

Issues

Value added

Access to the donation is felt to have improved the level of care and coverage, by increasing access to drug and health worker awareness and capacity. For example, the donation has facilitated use at primary hospital level (by doctors and pharmacists), as opposed to by specialists only at higher levels in the system. DPP is seen as a 'great help' in making a saving, and a good collaboration. Pfizer is viewed as a valued and flexible partner.

The reporting system is more stringent than existing practice, but it was widely felt that the wider system should be aspiring to these standards, in terms of patient and drug monitoring. Demonstrating to health workers the value of patient management information over time. The CMS and Essential Drugs Action Programme are working to improve wider reporting systems.

Criticisms

Current use of Diflucan® branded patient information materials is perceived by some to be 'clear advertising of a brand to clinicians and the general

public' and not in accordance with Botswana's national drugs policy (which specifies use of generic names in patient labelling, in line with WHO essential drugs policy). Should the donation cease or the government make alternative plans for procuring the drug, this could compromise prospects for generic substitution.

While serving a useful purpose in demonstrating a possible model for improved drug and patient management, the reporting system is burdensome in terms of time, and could be better adapted to country system. The system is a burdensome paper based one. Software support would ease the pressure. MOH has raised this issue with Pfizer. Training did not include pharmacists sufficiently or enough on facility reporting requirements.

All Diflucan® formulations are registered and specified in the MOU with government. MOH has requested paediatric suspension but has not received this regularly.

Comments

The private sector has no access to DDP, and purchases Diflucan® where indicated. Generic versions of fluconazole are not registered, and generics do not appear to be being imported or used by private sector importers or by Medical Aid Schemes. Low use of Diflucan is reported in the private sector. The cap on the annual insurance benefit limit means that patients with CM may be advised to go through the public sector for long-term maintenance, where they can access DDP. This has implications for the burden on public sector services.

Some 'confusion and clashes' were reported by some health professionals with respect to limited indications – Diflucan® must be purchased for other severe or chronic fungal infections (e.g. resistant vaginal candidiasis) on the basis of a special order form, on a named patient basis.

Discount arrangements with Accelerating Access Initiative companies

Assessment of disease in national/district plan

The HIV/AIDS prevalence amongst the adult population in Botswana is 37.4% (2003). Of about 300,000 people with HIV, about 110,000 are estimated as eligible for treatment. The ARV programme was first announced by the government in 2001, and initiated in 2002.

AAI initiative goal, objectives and strategy

The AAI was established in May 2000 to help increase access to HIV/AIDS care and treatment in developing countries, including high burden middle-income. It is now a partnership of five UN organisations (UNAIDS, WHO, UNICEF, UN Population Fund, and the World Bank), and seven research based companies: Abbott Laboratories, Boehringer-Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, F. Hoffmann La-Roche, Gilead Sciences and Merck & Co., Inc).

AAI increasingly provides a framework for bilateral company-government negotiations, without the direct involvement of UN organisations. A 2002 evaluation of the AAI indicated that a growing number of agreements to supply products at discount prices were made in this manner.

Conditionalities

Drugs need to be available at lowest price or free to end user. Government negotiated price is for distribution in public sector or government supported clinics. Less steep, but still significant discounts are also negotiated by wholesalers serving the private market, particularly for use by the insured sector.

Nature of partnership

MOH and the supplying companies in Botswana have individual 'gentlemen's agreements'. Companies are BI, GSK, BMS, Roche, and Abbott.

Programme start, stage of development and future plans

The GoB set up a cross-government task force for ARV drugs price negotiations in 2001, in view of its intention to launch an ARV treatment programme in 2001-2002. The decision to negotiate with these companies was made on the basis of a list of ARVs developed by the AIDS Clinical Management Sub Committee. The task force met with individual company representatives to agree initial supply arrangements and prices, according to the AAI framework. Thereafter, companies have continued to offer price reductions to Botswana, in line with company overall discount strategy development.

Governance arrangements, management and personnel

None specific to AAI. Discount offers are managed in line with normal MOH and CMS procedures for non-tendered procurements. Public Procurement Board approval was required for the initial negotiations with the companies and is also needed to ratify further price reductions offered.

Mode of operations

There is an ARV officer based at CMS whose responsibilities include drugs purchased from AAI companies. ARVs supplied through the agreements are operationally treated as schedule 1 'habit forming drugs' with high security provisions. Efforts have also been made to fast track drug registration and procurement processes, with shortened approval and ordering processes. The CMS and ARV programme uses projected number of patients to be treated and drug utilization reports from the facilities to make projections for the quantities required and forwards that to the National Coordinating Agency for the release of funds.

Budget and expenditure

Finance for ARV drug procurement is provided through the GoB's development budget AIDS allocation, as opposed to the MOH essential drugs budget. It already exceeds the latter, and amounts to about 50% of the ARV programme costs (not including donations).

Epidemiological and geographical coverage

A recent progress report from AAI companies (March 2004) states that the number of HIV patients in Africa receiving ARV treatments provided by AAI companies doubled from around 75,000 to 150,000 in the six months from June to December 2003. Botswana's 20,000 public and private sector patients contribute to this figure.

Issues

Value added

The ARV programme has been able to provide patients with quality assured and a regular and reliable supply of drugs as determined by national guidelines. Good relations are reported with companies, and there have been no problems with supply. Links are with South Africa company offices, which supports good communication. The overall approach to ARV security tightening is felt to be strengthening wider drug management, with the use of lockable container trucks and higher awareness among staff of leakage and pilferage risks.

Criticisms

Negotiations took place in 2001. The government has been benefiting from further price cuts as offered by the companies (e.g. GSK at end-2003). However, some informants felt that Botswana could adopt a more robust negotiating position, in view of its rollout plans. Others felt that patient volume would be too low to warrant additional discounts. Government does not systematically review comparative price information available from WHO, to strengthen its negotiating position. There is minimal information on prices achieved by different countries, in addition to the companies' listed offers.

Comments

There is a perception that the discount agreements with R&D companies mean that the MoH is restricted to use of their branded products only, which could limit use of cheaper generics. Some companies have also offered to provide continuing medical education and patient materials for HIV/AIDS and other unrelated conditions, as part of their broader support to improving access to effective treatment and care in developing countries. It is not clear whether the MoH has – or will – take up these offers.

ACHAP agreement

Merck offer of Stocrin® and Crixivan®

Country programme background/assessment of the disease/national health strategy and plan

The offer of Stocrin® and Crixivan® to the GoB is a component of the broader commitment by the Merck & Co., Inc. to address HIV/AIDS in Botswana. The African Comprehensive HIV/AIDS Partnership (ACHAP), a joint partnership between Merck/The Merck Company Foundation, the Bill & Melinda Gates Foundation and the Government of Botswana, engages in a comprehensive range of HIV/AIDS interventions in prevention, care and treatment.

The donation of Stocrin® and Crixivan® benefits the national anti-retroviral therapy (ART) pro-

gramme (MASA), one of the government's major HIV/AIDS programmes since January 2002. HIV/AIDS prevalence among 15-49 year olds in Botswana is 37.4% (2003). Stocrin® is prescribed as a part of a first line therapy regimen for all male and post-menopausal women. Crixivan®, while not part of first, second or third line regimens, is ordered in small amounts by CMS for some patients as per special requests by clinicians.

ART Programme Goal

To provide free treatment to all citizens of Botswana who qualify as per set criteria. The programme aims to roll-out provision of ART in 32 government and government-supported hospital facilities in districts across the country.

Stocrin® and Crixivan® were offered by Merck to support ACHAP's broader commitment to addressing HIV/AIDS. The donation of ART drugs was intended to supplement ACHAP's financial resources for various HIV/AIDS interventions covering prevention, care, treatment and support services.

Nature of the partnership and conditionalities

The donation is one of a range of ACHAP's inputs to the ART programme. ACHAP's contributions to the ART programme are widely recognized as some of ACHAP's most significant and successful initiatives. ACHAP has responded to a range of requests from the government to help government to meet the need for physical infrastructure, healthcare workers, information technology systems and information, education and communication for the ART programme.

ACHAP aims to engage in programmes initiated and largely implemented by the Government of Botswana. Accordingly, conditionalities associated with the prescription of donated drugs are largely those imposed by government on the prescription of various ARV drugs. The agreement between ACHAP and the government specifies the use of Crixivan and Stocrin® by public sector treatment programmes. Additionally, the government chose to use its own funds, rather than ACHAP's, to purchase other ART drugs.

Programme start date, stage of development and future plans

The donation of Stocrin® and Crixivan® began in January 2002. The donation was set to end with the end of ACHAP, in December 2005. With the extension of the expenditure of ACHAP funds through 2007, Merck is also reconsidering the period for donation of Stocrin® and Crixivan®.

Governance arrangements and location of manager

The ACHAP field office in Gaborone manages the donation from Merck to the Government of Botswana. The donation is supplied according to a standard operating procedure agreed between Merck and the government, setting out the ordering and delivery cycle. The Government of Botswana, through the Central Medical Stores (CMS), is responsible for providing ACHAP with monthly forecasts for quantities necessary for the ART programme. ACHAP communicates the forecast to Merck. Donated drugs are received and distributed by the CMS. CMS is responsible for providing ACHAP with a monthly status report on issue of the drugs. This report is compiled from data provided by various ART sites, with support from the ARV programme. Delivery is dependent on receipt of forecasts from CMS. As with other ARVs, drugs are stored and distributed according to schedule 1 standards for habit forming drugs.

Dedicated personnel

There are no personnel dedicated entirely to managing the donation of Stocrin® and Crixivan at the national level. Management of the donation programme is one of the many responsibilities of ACHAP's financial operations manager, personnel within the CMS and personnel responsible for managing Merck's various drug donations. ACHAP's financial manager spends some 5% of her time on managing the drug donation component of ACHAP.

At the district level, there are no personnel dedicated entirely to managing the donation of Stocrin® and Crixivan®. Pharmacists in health facilities with ART sites are responsible for secure storage and reporting on usage as well as various other drugs, using dedicated Schedule 1 drug registers (prescriber and named patient information). A CMS staff member is dedicated to managing ARV supply, distribution and security.

Budget and actual spend

There are no published figures on the value of the donation of Stocrin® and Crixivan®.

Current geographical and epidemiological coverage

ART is currently provided in 12 facilities across the country. In early 2004, over 24,000 patients had been enrolled in the national ART programme (public and private sectors) and over 14,000 patients have been initiated on ART in the public sector. By June 2004 the numbers had increased to 27,000 and 17,000, respectively. Approximately 55% of patients on ART are prescribed donated Stocrin®. By December, 2003, 46,146 units of Stocrin® 200mg 90s and 60 units of Crixivan® 200 mg 180s had been dispensed.

Sustainability measures

While the government is committed to maintaining the ARV Programme, there is little evidence of systematic accounting for the donation of Stocrin® within the national HIV/AIDS budget, nor of formal plans to absorb costs of these drugs beyond 2005.

To meet human resource requirements for a fully rolled out ART programme, the government is considering proposals for including private sector doctors in the delivery of national ART. It is also considering the possibility of redefining the roles of health care workers, to allow nurse practitioners to prescribe ARV refills and pharmacy technicians to dispense ARVs without on site supervision by a pharmacist. A change in roles would enable district clinics to take on greater responsibility for follow-up and monitoring of stable patients. This model would free up resources at hospital level for taking on new patients and for management of complex cases. It would also support adherence among patients, by reducing travel and waiting times. However, this policy change would require bolstering of capacity at facility level for strong supervision and support of staff at local clinics. Drug management issues would also need addressing to ensure drug security and reporting at clinic level, which are perceived to have some weaknesses.

Linkages with other programmes

Although one in three Batswana are HIV-positive, a far lower proportion knows that they are HIV-positive. Until the availability of treatment, there were few incentives to obtaining an HIV test. With the availability of ART, HIV/AIDS is no longer a death sentence but a chronic disease, for those who test positive. The ART programme is widely seen to have facilitated the establishment of routine testing for HIV/AIDS in all public health facilities, starting January 2004. Patients are referred to the ART programme for follow up. However, links with vertical health programmes such as TB, STIs and PMTCT are perceived as weak, where a 'dedicated' ARV team is running the ARV clinic. However, in some district hospitals, staff report good collaboration with other programmes, where TB patients and pregnant women with possible AIDS symptoms are referred for treatment registration. This trend is supported by the 'integrated' team model – where all facility clinicians are trained in ARV treatment management and work within the clinic on a rotation basis.

Issues

Value-added

There are few conditionalities attached to distribution and reporting for the donation of Stocrin® and Crixivan®. The donation, as one of ACHAP's contributions, is widely recognised to have bolstered government confidence towards starting its national ARV programme.

Comments

While the donation of Stocrin® and Crixivan® and ACHAP's various initiatives have been useful in starting up the ARV programme, the programme faces severe challenges in enabling equitable access for all citizens. Although ART is to be available free of charge to all Botswana citizens, access to ART is presently mitigated by the pace of ART programme roll out.

The pace has been relatively slow in view of the tremendous needs and expectations created in many districts. The challenges in meeting human resource requirement for establishing 32 sites has been cited as a key reason affecting the speed of programme roll out. The lack of reliable and affordable transport and other costs associated with obtaining and adhering to treatment available from distant sites, remain an issue for significant proportions of the population.

ANNEX 4

Compliance with interagency guidelines for drug donations and discounts at country level

Checklist for compliance with Interagency Guidelines for Drug Donations Revised 1999 (WHO/EDM/PAR/99.4)

	DIFLUCAN®	VIRAMUNE®	STOCRIN® AND CRIXIVAN®
All drugs should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent of the recipient.	Y	Y	Y
All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List of Essential Drugs, unless specifically requested otherwise by the recipient.	Y	Y	Y
The presentation, strength and formulation of donated drugs should, as much as possible, be similar to those of drugs commonly used in the recipient country.	Y	Y	Y
All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.	Y	Y	Y
No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.	Y	Y	Y
After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year.	Y	Y	Y
All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.	Y	Y	Y
As much as possible, donated drugs should be presented in larger quantity units and hospital packs.	Y	Y	Y
All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.	Y	Y	Y
Recipients should be informed of all drug donations that are being considered, prepared or actually under way.	Y	Y	Y
In the recipient country the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.	Varies	Varies	***
Costs of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.**	Y	Y	Y

** It is agreed that the government will clear from the port.

*** Under Merck's pricing policy for its ARVs Stocrin® & Crixivan®, Botswana would be eligible for Merck's "no-profit" prices US$ 600/yr for Crixivan®, US$ 500/yr for Stocrin® 200mg capsules, US$ 346.75 for Stocrin® 600 mg tablets

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Checklist for compliance with guidelines for price discounts of single-source pharmaceuticals (WHO/EDM/PAR/2003.3)

	ARV DISCOUNTS WITH AAI COMPANIES
1. The discount programme should aim to assist countries in promoting access The discount agreement should aim to assist countries in their efforts to achieve equitable and sustainable access to essential health care, including essential medicines. The programme should not be mainly promotional in character, nor should it be designed primarily to increase market opportunities for the company involved to the detriment of others.	Y
2. The eligible population should be selected on the basis of agreed criteria The countries and patient populations for which the pricing offer is made should be jointly selected on the basis of agreed justifiable criteria, such as health needs, expression of interest, political commitment, economic status, health system infrastructure and potential for sustainability.	Y
3. The product should be registered for the relevant indication in the country of destination	Y
4. The medicine should be recommended in a recognized clinical guideline The medicine should offer a cost-effective and safe treatment for the disease, and be recommended by an officially published WHO treatment guideline or included in the WHO Model Formulary. The medicine should preferably be included in a national or organizational treatment guideline and in the national list of essential medicines.	Y
5. The discounted price should be compared with prices of equivalent medicines The discounted price offered should be compared with the prices of the generic and therapeutic equivalents legally available on the world market.	N
6. Distribution and other costs should be estimated and funding assured Current and future additional funding requirements for the product and its transport, distribution, training and use should be estimated in advance and the funding should be assured. This also applies to additional costs to national and international organizations involved, such as meeting costs, travel costs and country visits.	Y
7. The scope of the offer should be clearly specified The scope of the discount (e.g. geographical areas, patient categories, products, volume and duration) should be clearly specified. If the discounted price is limited in scope or in time, these limitations must be clearly defined, and the needs of other patients and the long-term sustainability of the programme must be addressed.	Y
8. Diagnostic and clinical guidelines must be promoted, and treatment facilities available Diagnostic criteria and clinical guidelines for the effective use of the medicine must be defined and promoted. Health workers must have been trained and a supervision system must be in place. Diagnostic and treatment facilities must be available or be developed.	Y
9. Systems for supply and reporting must be defined The systems for supply, distribution, monitoring and reporting must be defined in advance. These systems should not create an undue burden for all concerned and should, as far as possible, be integrated within existing systems.	Y
10. The content of the discount agreement should be public Information regarding the content of the discount agreement and the experiences with the programme should be accessible to the public.	No written agreements but offers in line with company offers (public)

ANNEX 5

Bibilography

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The aim of the Initiative on Public-Private Partnerships for Health is to increase the effectiveness of public-private collaboration, particularly by helping those seeking to develop and improve access to health products to fight neglected diseases and other health problems in developing countries.

Created in 2000 in Geneva, Switzerland, the Initiative on Public-Private Partnerships for Health is sponsored by the Bill & Melinda Gates Foundation, the Rockefeller Foundation and the World Bank. It operates under the aegis of the Global Forum for Health Research, an independent international foundation helping to correct the 10/90 gap in health research, from which it also receives support (www.globalforumhealth.org).

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